



ACELRx ANNOUNCES POSITIVE RESULTS FROM A PHASE 2 STUDY OF ARX-03, A SUFENTANIL/TRIAZOLAM NANOTAB FOR PROCEDURAL SEDATION, ANXIOLYSIS & ANALGESIA

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AcelRx Pharmaceuticals, Inc. today announced positive results from a Phase 2 clinical trial of ARX-03, a proprietary sublingual dosage form combining an opioid, sufentanil, with a benzodiazepine, triazolam. ARX-03 is designed to address the current unmet need for a non-invasive product to provide mild sedation, anxiolysis and analgesia with rapid onset of action for the increasing number of painful and anxiety-producing office-based procedures. The objective of this randomized, double-blind, placebo-controlled study was assessment of safety, tolerability and efficacy of ARX-03 relative to placebo in patients undergoing an elective low-volume abdominal liposuction procedure.

In the study, 40 patients were randomized to received either a single sublingual dose of ARX-03 (sufentanil 15 mcg/triazolam 200 mcg NanoTab™) or placebo prior to the injection of a local anesthetic and the subsequent liposuction procedure. The primary endpoint was efficacy of ARX-03 compared to placebo in providing mild sedation during the procedure, as assessed using the validated, objective Richmond Agitation-Sedation Scale (RASS). The cumulative RASS score over the 4-hour study period was significantly better for active than for placebo ($p < 0.001$) and a separation from placebo was seen as early as 30 minutes post-dosing ($p = 0.046$), indicating a rapid onset of sedation. The placebo group averaged positive cumulative RASS values once the local anesthetic/procedure began, indicating an anxious and restless patient; the patients treated with ARX-03 demonstrated cumulative negative RASS values throughout the entire procedure, indicating a calm to mildly sedated patient. These data demonstrate both the need for a product such as this in the procedural setting, as well as the efficacy of ARX-03 in providing mild sedation during surgical procedures.

A key secondary endpoint was the efficacy of ARX-03 in reducing anxiety compared to placebo. The cumulative anxiety score (patient-reported 11-point scale) over 4 hours was significantly lower for active than for placebo ($p = 0.004$), and a separation from placebo was seen as early as 15 minutes post-dosing ($p = 0.034$), indicating a rapid onset of anxiolysis. The secondary endpoint of analgesic efficacy (Summed Pain Intensity) which reflects the cumulative pain score over the 4-hour study period was lower for the group treated with ARX-03 relative to those treated with placebo (median values of 13 versus 23 in the active and placebo groups, respectively; $p = 0.09$). In addition, both physician and patient global evaluations of effectiveness and tolerability were significantly higher in the active versus placebo groups ($p < 0.001$ and $p = 0.028$, respectively).

Lead investigator, Dr. Neil Singla, commented, "The strong safety profile and high global satisfaction ratings speak to the advantages of this product. The blinded Physician Global Efficacy rating of 'Very Good' or 'Excellent' for 62% of the active patients versus 5% for the placebo patients demonstrates both the utility and efficacy of this product. I think this product has exceptional promise as a routine pre-procedure treatment appropriate for many different office-based procedures, especially since the discharge readiness was not different between active and placebo groups."

Pamela Palmer, MD, PhD, AcelRx Chief Medical Officer stated, "There is a growing need for a safe, non-invasive, rapid-acting medication explicitly developed for use in relieving patients' pain and anxiety during painful outpatient procedures, such as breast and prostate biopsies, performed in the clinician office setting. We are developing ARX-03 to meet this need, and with this first Phase 2 study, we have laid the groundwork by demonstrative that ARX-03 can be dosed just prior to a procedure and produce safe, objectively measured mild sedation, along with anxiolysis and analgesia with rapid onset, that should translate into a meaningful improvement in both the patient and physician experience."



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