



AcelRx Announces Positive Results from a Phase 2 Study of ARX-03, a Sufentanil/Triazolam NanoTab for Procedural Sedation, Anxiolysis & Analgesia

REDWOOD CITY, Calif., October 22, 2009 -- 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 receive 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 demonstrating 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."

About Procedural Pain and Anxiety

The number of minimally invasive procedures performed outside of the typical operating room setting has grown significantly over recent years. Despite the prevalence of office-based surgical procedures, most clinics cannot provide appropriate staffing/monitoring mandated by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) for intravenous analgesia and sedation, nor do these procedures require this moderate to deep level of sedation. As a result, patients undergoing these procedures often receive only local anesthetics and consequently experience high levels of pain and anxiety. Ideally, treatment of procedural pain and anxiety minimizes patient discomfort and agitation, while maintaining patient safety. A preferred product candidate for treatment of procedural pain and anxiety is safe and

possesses mildly sedative and analgesic properties, has rapid onset and a sufficient, but short duration of action, allowing rapid recovery and discharge.

About ARX-03

ARX-03 is designed to provide mild sedation, anxiolysis and analgesia in a safe, non-invasive formulation that is easy to administer sublingually in procedural settings and provides rapid onset of action. ARX-03 is based on the AcelRx's proprietary NanoTab™ dosage form, which enables delivery of the sufentanil/triazolam combination by the oral transmucosal route, resulting in high drug bioavailability but significantly lower and safer peak plasma levels than the intravenous route. AcelRx has previously reported results of a Phase 1 study demonstrating the safety, tolerability and pharmacodynamic efficacy of ARX-03 in healthy volunteers.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals is a privately held pharmaceutical company dedicated to the development and commercialization of new therapies for the treatment of pain and other conditions where there is an unmet need for improved safety and efficacy. The company applies its proprietary dosage form and delivery technologies to enhance the safety, therapeutic benefit and commercial attractiveness of currently approved compounds. For additional information about AcelRx Pharmaceuticals visit <http://www.acelrx.com>.

Contact:

AcelRx Pharmaceuticals, Inc.

Nigel Ray, MBA

Vice President, Business Development

650-216-3500

info@acelrx.com