



**AcelRx Pharmaceuticals Reports Positive Results from a Clinical Trial of Sublingual Sufentanil/Triazolam NanoTab™ Combination (ARX-03) in Treating Procedural Pain and Anxiety**

***Results Show Successful Clinical Validation of Pharmacodynamic Effect***

REDWOOD CITY, Calif., January 12, 2009 -- AcelRx Pharmaceuticals, Inc., an emerging specialty pharmaceutical company focused on the treatment of intermittent and acute medical conditions with an initial emphasis on pain management, today announced positive results from a Phase 1 clinical study evaluating the safety, tolerability and efficacy of the company's proprietary sublingual sufentanil (opioid) and triazolam (benzodiazepine) NanoTab™ combination product candidate (ARX-03). The product is designed to address the current unmet need for a non-invasive product to provide sedation and analgesia for an increasing number of office-based procedures.

The study demonstrated that administration of ARX-03 resulted in a statistically significant increase in sedation levels for the 10mcg sufentanil/200mcg triazolam dosage strength in both a younger cohort (age range 18-60 years;  $p=0.009$ ) and an older cohort (age range of 61-80 years;  $p=0.003$ ) as compared to sublingual sufentanil alone. These data were collected using the Richmond Agitation-Sedation Scale (RASS), a validated and objective test for assessment of sedation levels. The average onset of sedation was 20-30 minutes for the higher dosage strength in each study cohort.

Additionally, sublingual administration of the sufentanil/triazolam combination was found to be safe and well tolerated. Based on these positive results, AcelRx intends to further advance clinical development of ARX-03 in 2009.

"We believe the results of this trial are particularly valuable as they offer clinical evidence well beyond what is expected from a typical Phase 1 study. Not only have we shown ARX-03 to be safe and well-tolerated, we have also demonstrated significant pharmacodynamic findings with a randomized, double-blind design that spanned different age groups and multiple dosage levels," said Pamela Palmer, M.D., Ph.D., chief medical officer of AcelRx Pharmaceuticals.

This 24-patient two-cohort, five-arm crossover study included administration of open-label oral triazolam and IV sufentanil on days one and two followed by a double-blinded, randomized dosing of a sublingual NanoTab™ containing high-dose sufentanil/triazolam, low-dose sufentanil/triazolam and 10mcg sufentanil only on days three to five.

ARX-03 is designed to provide analgesia, anxiolysis and mild sedation without requiring the presence of an anesthesiologist, in a safe, simple, non-invasive form for use in procedural settings. The product is based on the company's proprietary NanoTab™ dosage form, which enables delivery of the sufentanil/triazolam combination by the non-invasive oral transmucosal (sublingual) route, resulting in high drug bioavailability but significantly lower and safer peak plasma levels than IV.

"The very positive data generated from this study validates the clinical applicability of this product concept from both a safety and efficacy point of view, and further underscores the commitment of AcclRx to advance the clinical development of this program," said Thomas A. Schreck, chairman and chief executive officer of AcclRx Pharmaceuticals. "The positive findings that AcclRx recently announced regarding our lead product candidate, ARX-01, combined with the impressive data from this ARX-03 study demonstrate the breadth and value of the AcclRx pipeline and strongly positions the company for future success."

### **About ARX-03 Sublingual Sufentanil/Triazolam NanoTab™ Combination for Procedural Pain and Anxiety**

Procedural pain and anxiety in the doctor's office and clinic setting represents a significant unmet medical need for patients and healthcare providers. Most physician's offices and clinics cannot provide appropriate staffing for IV sedation, often resulting in patients experiencing high levels of pain and anxiety. Ideal treatment of procedural pain and anxiety minimizes patient awareness and discomfort, while maintaining patient safety. A preferred product candidate for treatment of procedural pain and anxiety should possess sedative, analgesic and amnestic properties, be safe, easy to use and administered via a non-invasive route, and have a rapid onset and a sufficient duration of action which allows for rapid recovery and discharge. AcclRx's novel ARX-03 sublingual NanoTab™ is designed to satisfy these criteria.

AcclRx is preparing to initiate a Phase 2a clinical trial to further evaluate the safety and efficacy of ARX-03 for treatment of procedural pain and anxiety.

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

AcclRx 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 AcclRx Pharmaceuticals visit <http://www.acclrx.com>.

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