A randomized, double-blind, placebo-controlled, Phase 2 study to evaluate the clinical efficacy, safety and tolerability of ARX-03 sublingual Sufentanil/Triazolam NanoTabs in patients undergoing an elective abdominal liposuction procedure

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Description:

Many patients are anxious and uncomfortable during office-based aesthetic, diagnostic and therapeutic procedures, which can negatively impact both the patient and the surgeon. ARX-03 is a new sublingual product combining sufentanil with triazolam and is in development to provide mild sedation, anxiolysis and analgesia with rapid onset of action for painful office-based procedures. Since ARX-03 is designed for Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) Level 1 sedation (minimal sedation), administration of ARX-03 will not require the level of staff monitoring mandated for intravenous sedation. In this randomized Phase 2 study, 40 patients undergoing low-volume liposuction received either a single sublingual dose of ARX-03 (sufentanil 15 mcg/triazolam 200 mcg NanoTab) or placebo prior to injection of a local anesthetic. The primary endpoint was mild sedation during the procedure, as assessed using the validated, objective Richmond Agitation-Sedation Scale (RASS). The summed RASS score over the 4-hour study period showed significantly greater sedation for ARX-03 than for placebo (p <0.001) and a separation from placebo was seen as early as 30 minutes post-dosing (p=0.046). The summed anxiety score (patient-reported 11-point scale) over 4 hours was also significantly lower for ARX-03 than for placebo (p=0.004), with separation from placebo occurring at 15 minutes post-dosing (p=0.034). 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) and all patients were ready for discharge immediately following the procedure, as measured by the modified Aldretti score. Adverse events were minimal and no respiratory depression was observed. The ARX-03 Sufentanil/Triazolam NanoTab demonstrated effectiveness and high tolerability in providing mild sedation with rapid onset for office-based procedures. Future studies of the Sufentanil/Triazolam NanoTab will further delineate the safety and efficacy of this novel product. Supported by a grant from AcelRx Pharmaceuticals, Inc.