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Safety and Efficacy of Sufentanil Sublingual 30 mcg Tablets for the Treatment of Acute Pain following Outpatient Abdominoplasty

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INTRODUCTION: The sufentanil sublingual tablet system is a non-invasive, patient-controlled analgesia (PCA) drug/device product recently approved by the European Medicines Agency for treatment of acute moderate-to-severe post-operative pain in a hospital setting. A second sufentanil product, a 30 mcg tablet (ST) dispensed sublingually by a healthcare professional via a single-dose applicator, is in Phase 3 development for treatment of moderate-to-severe pain in medically-supervised settings, such as outpatient or ambulatory surgery. Sublingual sufentanil appears well-suited for short duration acute pain management because it acts rapidly (plasma-CNS equilibration time of 6 minutes), does not require an invasive route of delivery and possess a predictable off-set, in part due to lack of active metabolites. The primary objective of this study was to compare the efficacy and safety of the ST to placebo tablet (PT) for the management of moderate-to-severe acute pain following typical outpatient abdominal surgeries.

METHODS: The study was multicenter, randomized and placebo-controlled for up to 48 hours in adult patients undergoing the following outpatient abdominal surgical procedures: abdominoplasty, open tension-free inguinal hernioplasty or laparoscopic abdominal surgery. Following IRB approval and patient informed consent, approximately 180 patients who met all inclusion and none of the exclusion criteria were randomly assigned at a 2:1 ratio to treatment with ST or PT. Efficacy was assessed by patient reports of pain intensity on an 11-point numerical rating scale (0 = no pain, and 10 = worst possible pain) and a five-point pain relief scale (0 = no relief, 4 = complete relief). The primary efficacy variable was the summed pain intensity difference to baseline over the 12-hour study period (SPID12). Safety was assessed via periodic measurement of vital signs, continuous monitoring of oxygen saturation, spontaneously reported adverse events (AEs) and the use of concomitant medications.

RESULTS: A total of 161 (107 ST and 54 PT) patients were randomized and received study drug. Average patient age was 41 years, 68% were female and approximately 50% had undergone abdominoplasty surgery. Statistically significant SPID12 differences were observed in favor of ST over PT (25.8 vs. 13.1; $p<0.001$) for the entire cohort, demonstrating superiority of sublingual sufentanil 30mcg for management of acute post-operative pain. Subgroup analysis by surgery type, despite much smaller sample sizes, also yielded significantly higher scores for ST over PT for abdominoplasty patients (30.8 vs 17.6; $p=0.001$). Most AEs were mild to moderate in severity with nausea and headache as the most common across both treatment arms.

DISCUSSION/CONCLUSION: The sufentanil sublingual 30 mcg tablet has shown benefit over placebo across a range of surgical procedures as a non-invasive analgesic modality requiring short-term treatment of acute moderate-to-severe pain.