Safety and Efficacy of Sufentanil Sublingual Tablet 30mcg for the Treatment of Acute Pain

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INTRODUCTION: Burns often happen unexpectedly and have the potential to cause death, lifelong disfigurement and dysfunction. Burn injuries are the third leading cause of accidental death in the U.S., with more than 1 million people seeking medical care for burns each year. More than 95% of these patients can be managed on an ambulatory basis however, and as practitioners implement the systematic approach to burn injuries that focuses on the six "Cs": clothing, cooling, cleaning, chemoprophylaxis, covering and comforting (pain relief), there remains a clinical need for rapid-acting, potent analgesics that do not require an invasive route of delivery. A 30 mcg sufentanil tablet (ST30) dispensed sublingually is in Phase 3 development for treatment of moderate-to-severe acute pain in medically-supervised settings, such as the Emergency Department, Burn Centers or field trauma situations.

METHODS: The primary objective of this study was to compare the efficacy and safety of the ST30 to placebo for the management of moderate-to-severe acute pain following ambulatory surgery. The study was multicenter, randomized and placebo-controlled in adult patients undergoing laparoscopic abdominal surgery, hernia or abdominoplasty. 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 the primary efficacy variable was the time-weighted Summed Pain Intensity Difference to baseline over the 12-hour study period (SPID12). Key secondary endpoints included time to perceived and meaningful pain relief and percentage of patients terminating early due to inadequate analgesia. Safety assessments included vital signs, oxygen saturation, spontaneously reported adverse events (AEs) and use of concomitant medications.

RESULTS: A total of 161 patients (107 ST30 and 54 placebo) were randomized and received study drug. Average patient age was 41 years; 68% were female. Statistically significant differences ($p<0.001$) in favor of ST30 were observed for SPID12, with separation between the two cohorts noted as early as 15-minutes post dose. Approximately six times as many placebo patients dropped out of the study due to inadequate analgesia (3.7% vs 18.5%). The type and

frequency of adverse events were typical of opioids in a post-operative setting with nausea, and vomiting more common in the active drug cohort.

DISCUSSION/CONCLUSION: The sufentanil sublingual 30 mcg tablet has shown benefit over placebo as a non-invasive analgesic modality in medically supervised settings requiring short-term treatment of acute moderate-to-severe pain. Additional emergency medicine studies are ongoing to assess potential applications for management of burn victims.