Efficacy and Safety of Sublingual Sufentanil for the Management of Acute Pain Following Ambulatory Surgery

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Introduction: Ambulatory surgery, coming to and leaving the hospital on the same day as surgery, is increasingly being adopted. Early discharge demands a rapid recovery and low incidence and intensity of surgery-related side-effects, so there remains a clinical need for rapid-acting, potent analgesics that offer predictable offset and good tolerability. A sufentanil sublingual 30mcg tablet (ST), dispensed using a single-dose applicator, is in phase 3 development for treatment of moderate-to-severe acute pain and could offer potential analgesic advantages in ambulatory surgery or other venues requiring non-invasive, acute pain management.

Materials and Methods: The primary objective of this study was to demonstrate the efficacy, safety and tolerability of ST compared to placebo (PT) for the management of acute pain as determined by the time-weighted sum of pain intensity differences to baseline over the 12-hour study period (SPID12). Key secondary endpoints included SPID over the first hour of the study, total pain relief and proportion of patients rating the method of pain management as “good” or “excellent”. Safety assessments included adverse events (AEs), vital signs, oxygen saturation and the use of concomitant medications.

Results: A total of 161 (107 ST and 54 PT) patients were randomized and received study drug. Statistically significant SPID12 differences were observed in favor of ST over PT (25.8 vs.13.1; $p<0.001$), demonstrating superiority for management of acute post-operative pain. AEs in general were mild to moderate in severity with the type and frequency observed, typical of opioids in a post-operative setting. Nausea (29% vs 22%), headache (12% vs 11%) and vomiting (6% vs 2%) were the most common treatment-related AEs for the ST and PT treatment arms, respectively.

Conclusions: Efficacy and tolerability results from this study suggest that sufentanil 30mcg tablets dispensed sublingually via single-dose applicator may offer a viable alternative to IM or IV dosing in an ambulatory surgery population.