The Sufentanil Sublingual 30mcg Tablet and Effect of BMI on Post-Operative Pain Management Following Outpatient Abdominal Surgery

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BACKGROUND: Obesity is the most prevalent chronic disease in the U.S. When surgery is indicated in this population, obesity-related comorbidities can sharply increase surgical risk and challenge post-operative analgesia regimen. A sufentanil sublingual 30mcg tablet (SST) is in Phase 3 development for treatment of moderate-to-severe acute pain. Dispensed by an HCP, SST appears well-suited for short duration pain management, as it acts rapidly (plasma-CNS equilibration time = 6 minutes), does not require an invasive route of delivery and possesses a predictable off-set, due to lack of active metabolites. The primary objective of this study was to compare the efficacy and tolerability of SST to placebo (PBO) for management of post-operative pain following outpatient abdominal surgery.

METHODS: This was a randomized (2:1 SST vs PBO) controlled trial of adults undergoing short-stay abdominal surgery. Efficacy was assessed by patient reports of pain intensity on an 11-point numerical rating scale. Primary efficacy variable was the summed pain intensity difference to baseline over the 12-hour study period (SPID12). Subgroup analysis by BMI was also performed a priori. Safety was monitored via vital signs, adverse events (AEs) and use of concomitant medications.

RESULTS: A total of 161 patients were randomized. Approximately 50%, 30% and 20% respectively underwent abdominoplasty, laparoscopic surgery and hernia repair. For all patients, statistically significant SPID12 differences were observed in favor of SST over PBO (25.8 vs. 13.1; $p<0.001$), with subgroup analysis by BMI also yielding numerically higher SPID12 scores (greater pain relief) for patients with a BMI $\geq 30 kg/m^2$, however sample sizes were limited. Nausea, headache and vomiting were the most common AEs across both treatment arms.

CONCLUSION: SST has shown benefit over placebo across a range of BMI and surgical procedures as a non-invasive analgesic modality requiring short-term treatment of acute moderate-to-severe pain.