Safety and Efficacy of the Sufentanil Sublingual Tablet 30mcg for Treatment of Moderate-to-Severe Acute Pain in the Emergency Department

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INTRODUCTION: Outcomes for burn patients have improved dramatically over the past 20 years, yet burns still cause substantial morbidity and mortality.[1] Proper early evaluation and management, coupled with appropriate referral, greatly help minimize suffering and optimize results.[2,3] In the United States, approximately 1.25 million people with burns present to the emergency department (ED) each year. Among these, 63,000 have minor burn injuries that are treated and released with an additional 6000 sustaining major burn injuries, requiring hospital admission.[4] Given the painful nature of burns and that frequently they affect upper extremities and torso, there remains a clinical need for rapid-acting, potent analgesics that do not require an invasive route of delivery. A 30 mcg sufentanil tablet (SST30) dispensed sublingually (SST30) recently completed Phase 3 development for treatment of moderate-to-severe acute pain in medically-supervised settings, such as an ED, burn center or field trauma situation.

METHODS: The primary objective of this multi-center, open-label study was to assess the safety and efficacy of SST30 for the management of acute moderate-to-severe pain in adut patients presenting to the ED with trauma or injury. The first 40 patients were administered a single dose of SST30 and remained in the study for up to 2 hours, while subsequent patients were allowed up to 3 additional doses, to be given no more frequently than every 60 minutes. Patients must have reported a pain score of ≥4 on an 11-point numerical rating scale (NRS 0-10) before first dose of study drug could be given. The primary efficacy variable was the summed pain intensity difference to baseline over the first hour (SPID1). Safety assessments included vital signs, oxygen saturation, spontaneously reported adverse events (AEs) and a six-item cognitive screener (SIS).

RESULTS: A total of 76 patients were enrolled; mean age was 42. Mean baseline pain intensity was 8.1/10 (“severe” pain) with injuries that included fractures, soft tissue damage, dislocations, lacerations and burns. Substantial reductions in pain intensity (mean 2.9/10 or >35%) were observed within 60 minutes. 60/76 patients (79%) reported no AEs, with nausea (9%) and somnolence (5%) the most common,

DISCUSSION/CONCLUSION: The sufentanil sublingual tablet 30 mcg has shown benefit 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 necessary to assess potential applications for management of more complex burn injuries.

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