A Phase 2 Multicenter, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy, Safety, and Tolerability of Oral-Sublingually Administered Sufentanil NanoTab™ in Patients Following Major Abdominal Surgery

**Abstract**

**Background and Objectives**

In severe acute patient-controlled analgesia (PCA) with morphine is the standard of care in many

**Methodology**

- **Patients**: 109 patients following major abdominal surgery randomized to receive placebo, 10 mcg or 15 mcg doses of Sufentanil NanoTab. Study drug was self-administered sublingually as needed to treat pain at patient's request, with 20-minute minimum and 12-hour maximum dosing interval. Patients were allowed a maximum of 24 doses over 12-hour study period.

- **Study drug administration**: Study drug was nurse-administered sublingually as needed to treat pain at patient's request, with 20-minute minimum and 12-hour maximum dosing interval. Patients were allowed a maximum of 24 doses over 12-hour study period.

- **Evaluation of pain relief (p<0.001)**: For ITT population, statistically significant differences between treatment groups and placebo for last evaluation of pain relief (p<0.001)

- **Results**: Results from the Phase 2 study showed that sublingually administered Sufentanil NanoTab was effective and safe in the management of moderate-to-severe post-operative pain in patients after major abdominal surgery. The study drug was well tolerated, with no serious adverse events reported. The median time to first re-medication was 118.9 minutes in the 10 mcg group and 100.7 minutes in the 15 mcg group, respectively, which is longer than typical interdosing intervals for IV PCA.

- **Conclusion**: The Phase 2 study demonstrated the feasibility, efficacy, and safety of a sublingual formulation of sufentanil in the management of moderate-to-severe post-operative pain after major abdominal surgery. Further studies are needed to evaluate the clinical effectiveness and safety of Sufentanil NanoTab in a broader patient population.

**References**

6. ASRA 2009 Poster A1222.
7. 21 (70.0%) patients in placebo group discontinued due to inadequate analgesia.
8. Median time to first re-medication was shorter in the placebo group compared to the Sufentanil NanoTab groups.
9. No clinically significant changes in laboratory variables, vital signs, or oxygen saturation during the study.
10. No adverse events related to study drug.
11. No reports of oral mucosa irritation.
12. No serious adverse events related to study drug.
13. No clinically significant changes in laboratory variables, vital signs, or oxygen saturation during the study.
14. All patients received study drug and were included in the ITT analysis.
15. n=30
16. * p < 0.001 vs. placebo

**Figure 1.** SPID Scores Over the 12-Hour Study Period

**Figure 2.** Discontinuation Due to Inadequate Analgesia

**Figure 3.** Patient Global Evaluation of Pain Relief

**Table 1.** Median Time to First Re-Medication

**Table 2.** Adverse Events

**Table 3.** Somnolence

**Table 4.** Nausea

**Table 5.** Pain Intensity and Pain Relief Scores Using Electronic Diary Evaluation of Pain Relief

**Table 6.** Proportion of Patients that responded 'good', 'very good' or 'excellent' in Patient Global Evaluation of Pain Relief.