Methods (Cont)

Efficacy Assessments

• The primary efficacy variable (endpoint) was the time-weighted summed pain intensity difference to baseline over the 12-hour study period (SPID12).

• Key secondary endpoints included time-weighted summed pain intensity difference over the first hour of the study period (SPID1), total pain relief (TOSTPAR), proportion of patients and healthcare professionals who responded “good” or “excellent” to the global assessments (PGA and PSQ) and proportion of patients who terminated early from the study due to inadequate analgesia.

Safety Assessments

• Safety assessments included spontaneously reported adverse events (AEs), vital signs (blood pressure, heart rate, and respiratory rate), oxygen saturation, and the use of concomitant medications.

Results

Baseline Demographics and Patient Disposition

• A total of 161 (107 ST and 54 PT) patients were randomized and received study drug. Average patient age was 41 years; 68% were female.

• Baseline demographics were evenly distributed between treatment arms with approximately 50%, 30% and 20% of the patients undergoing abdominoplasty, laparoscopic surgery and hernia repair, respectively.

• Five times as many patients in the PT cohort terminated early from the study due to ‘Lack of Efficacy’ compared to the ST cohort (18.5% vs. 3.7%).

Efficacy

• 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.

• Several secondary endpoints also met statistical significance in favor of ST including TOSTPAR, PGA, HPGA and summed pain/pain relief composite measure (p<0.001 for all).

• Figure 2 illustrates the differences in SPID over the first hour of treatment, with statistically significant separation between the two cohorts as early as 15 minutes from dosing (p=0.01).

Results (Cont)

Safety

• AEs in general were mild to moderate in severity with the type and frequency observed typical of opioids in a post-operative setting.

• Nausea, headache and vomiting were the most common treatment-emergent AEs across both treatment arms.

• Table 1 includes AEs ≥4% and considered “probably” or “possibly” related to study drug.

Table 1. Adverse Events Considered “Possibly” or “Probably” Related (≥4% in any group)

<table>
<thead>
<tr>
<th>Treatment Arm</th>
<th>Sufentanil Tablet (n = 109)</th>
<th>Placebo Tablet (n = 54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>11 (29)</td>
<td>12 (22)</td>
</tr>
<tr>
<td>Headache</td>
<td>13 (12)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>6 (6)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>6 (6)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Somnolence</td>
<td>3 (3)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>2 (2)</td>
<td>2 (4)</td>
</tr>
</tbody>
</table>

Conclusion

• 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.

• Nausea and headache were the most commonly reported AEs for both treatment arms.

• Additional studies are indicated to assess potential applications within emergency medicine or other medically supervised venues.

References


Acknowledgements: AcelRx Pharmaceuticals (Redwood City, CA), the study sponsor, wishes to thank the study sites, PhamarNet(r), a subsidiary of Invention Health Clinical Research, the Clinical Coordinators and the Investigators.