HTX-011, a Proprietary, Extended-Release Combination of Bupivacaine and Meloxicam, Reduced Pain Intensity and Opioid Consumption for 96 Hours Following Abdominoplasty

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OBJECTIVE
To assess the safety and efficacy of HTX-011 in reducing pain intensity and opioid consumption after complete abdominoplasty

METHODS
Study Design
The study included a cohort of subjects participating in an ongoing randomized, multicenter, double-blind, placebo-controlled phase 2 IRB-approved clinical trial (NCT02689258). Based on initial dose-finding cohorts, a 400 mg dose of HTX-011 was selected after ongoing informed consent, subjects were screened to select those who were qualified for complete abdominoplasty

Subjects were randomly assigned 1:1 to single-dose administration of either:
- 400 mg HTX-011 (equivalent to 400 mg bupivacaine base) via a combination of injection and instillation
- Normal saline injection

Subjects were evaluated postoperatively for their pain and opioid use through 96 hours after study drug administration. When study drug administration completed, subjects were discharged. Follow-up visits were scheduled at 96 hours, 10 days, and 28 days after study drug administration

Subjects
Key inclusion criteria:
- American Society of Anesthesiologists Class I or II adults aged ≥18 years scheduled for complete abdominoplasty (NCT02689258)
- Adequate management of pain not only increases patient comfort, it prevents a cascade of adverse clinical outcomes for patients and increases costs for the health care system2
- Systemic opioids are often relied on for postoperative pain management, increasing the risk of opioid-related adverse events and the potential for drug abuse and addiction6

Baseline Population Characteristics
A total of 41 women (76% white, mean age 42 years, mean BMI 27) were enrolled and received treatment with either HTX-011 (n = 20) or saline placebo (n = 21) (Table 1)

RESULTS
Efficacy
Subjects treated with HTX-011 tended toward lower mean SPI scores for the first 24 hours and reported significantly lower mean SPI scores through 48, 72, and 96 hours after treatment than saline placebo recipients. Subjects treated with HTX-011 demonstrated significantly lower mean SPI scores in the 24 to 48, 48 to 72, and 72 to 96 hour time intervals (Figure 1)

Safety
No deaths, serious TEAEs, or TEAEs leading to premature discontinuation were reported

CONCLUSIONS
These results confirm the versatility of HTX-011, which has previously demonstrated efficacy in both herniorrhaphy14 and hernioplasty13 (see Post 3758) and now in abdominoplasty, which has a much larger incision

ACKNOWLEDGMENTS
This study was supported by Heron Therapeutics, Inc., San Diego, CA. Medical writing and editorial assistance was provided by ApolloCom (San Francisco, CA)

REFERENCES

Presented at the 42nd Annual Regional Anesthesiology & Acute Pain Medicine Meeting; April 6-8, 2017; San Francisco, CA