HTX-011: No Evidence of Local Anesthetic Systemic Toxicity

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INTRODUCTION

• HTX-011 is an investigational dual-acting local anesthetic formulation comprising bupivacaine and meloxicam in an extended-release polymer
• Development of LAST is generally associated with plasma concentrations of bupivacaine exceeding 400 mg bupivacaine/12 mg meloxicam
• Vascularity of the injection site is an important factor that influences plasma concentrations of bupivacaine

METHODS

• Phase 3 HTX-011 studies included assessment of potential LAST-related AEs
• Phase 3 studies evaluated HTX-011 in patients undergoing herniorrhaphy (NCT03237481), total knee arthroplasty (NCT03295721), and augmentation mammoplasty (NCT03011333)
• All patients received HTX-011, bupivacaine HCl, or placebo
• HTX-011 administration was performed without a needle

RESULTS

• No significant difference was observed in the incidence of potential LAST-related AEs between patients who did or did not receive any bupivacaine (data on file)
• At the highest recommended dose of HTX-011 (400 mg bupivacaine/12 mg meloxicam), the incidence of potential LAST-related AEs was lower than that of bupivacaine HCl alone or in combination with meloxicam

DISCUSSION/CONCLUSIONS

• No evidence of LAST was observed with HTX-011 in any study, even at the highest dose of 400 mg bupivacaine/12 mg meloxicam
• HTX-011 administration without a needle further reduces the risk of inadvertent intravascular injection

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REFERENCES


Figure 1. HTX-011 is Administered Without a Needle into the Surgical Site

Table 1. Incidence of Potential LAST-Related Adverse Events Across Surgeries

Table 2. Incidence of Potential LAST-Related Adverse Events in Phase 3 Studies, N (%)