Efficacy and Safety of N1539, Intravenous Meloxicam, in a Phase 3 Study of Subjects with Moderate to Severe Pain following Abdominoplasty

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ABSTRACT

Purpose: To conduct a randomized, double-blind, placebo-controlled study in subjects undergoing abdominoplasty surgery to evaluate the efficacy and safety of N1539 (IV meloxicam 30 mg) compared to placebo, and to support label claims for this agent for this indication. The study design involved 1,139 subjects enrolled to receive IV meloxicam 30 mg or placebo.

Methods: A randomized, double-blind, placebo-controlled, Phase 3 study was conducted to evaluate the efficacy and safety of IV meloxicam 30 mg using a 1:1 treatment ratio. Subjects ≥ 18 years of age with moderate-to-severe pain following abdominoplasty surgery were randomized to receive IV meloxicam 30 mg or placebo. The primary efficacy endpoint was the placebo-subtracted treatment effect (PTTE) of IV meloxicam 30 mg on the Pain Intensity Difference (SPID) at 24 hours following Dose 1. Secondary endpoints included the number of subjects with ≥30% improvement in pain reduction at 24 hours, and number of rescue doses used during the first 0-24 and 24-48 hour assessment periods.

Results: N1539 demonstrated a statistically significant reduction in pain intensity difference (SPID) after Dose 1 (p=0.0050) and 48 hours post Dose 1 (p=0.0434) compared to placebo in the pain intensity difference at 24 hours (p=0.0275) and from 24 to 48 hours (p=0.0009) following Dose 1. N1539 also improved pain intensity at 4 hours post Dose 1 (p=0.0009), with smaller reduction in pain intensity at each subsequent visit through 48 hours. The number of subjects with ≥30% improvement in pain reduction at 24 hours was numerically favored with N1539 compared to placebo (p=0.0178). N1539 also demonstrated a statistically significant reduction in the primary endpoint of time to administration of rescue analgesics during the first 24 hours (p=0.0119) and from 24 to 48 hours (p=0.0050). N1539 was associated with a statistically significant reduction in surgical wounds, with investigator satisfaction rated using a 0 to 10 scale (p=0.0001).

Conclusions: N1539 was associated with a statistically significant reduction in both pain intensity and time to rescue analgesics following Dose 1 in the first 24 hours and from 24 to 48 hours, along with other pain endpoints. The use of proprietary NanoCry technology has been shown to provide enhanced solubility of the active ingredient, meloxicam, leading to improved pharmacokinetic properties compared to parenteral formulations. N1539 has been shown to be safe and well tolerated, with a generally favorable safety and tolerability profile. This Phase 3 study supports the label claims for N1539 for the treatment of moderate-to-severe pain following abdominoplasty surgery.

REFERENCES

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