Study REC-15-015

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Efficacy and Safety of N1539 Following Abdominoplasty

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Study REC-15-015

Study Design

- Multicenter, Multi-dose, Randomized, Double-blind, Placebo-controlled

- 219 subjects randomized to IV Meloxicam (N1539) 30 mg or Placebo
  - Study medication administered q24 hours up to 3 doses
  - 98% of subjects completed the 48 hour assessments

- Standard analgesia design
  - Pain Intensity assessments (SPID24 = Primary Endpoint)
  - Use of rescue medication
  - Time to onset
  - Patient Global Assessment of Pain Control

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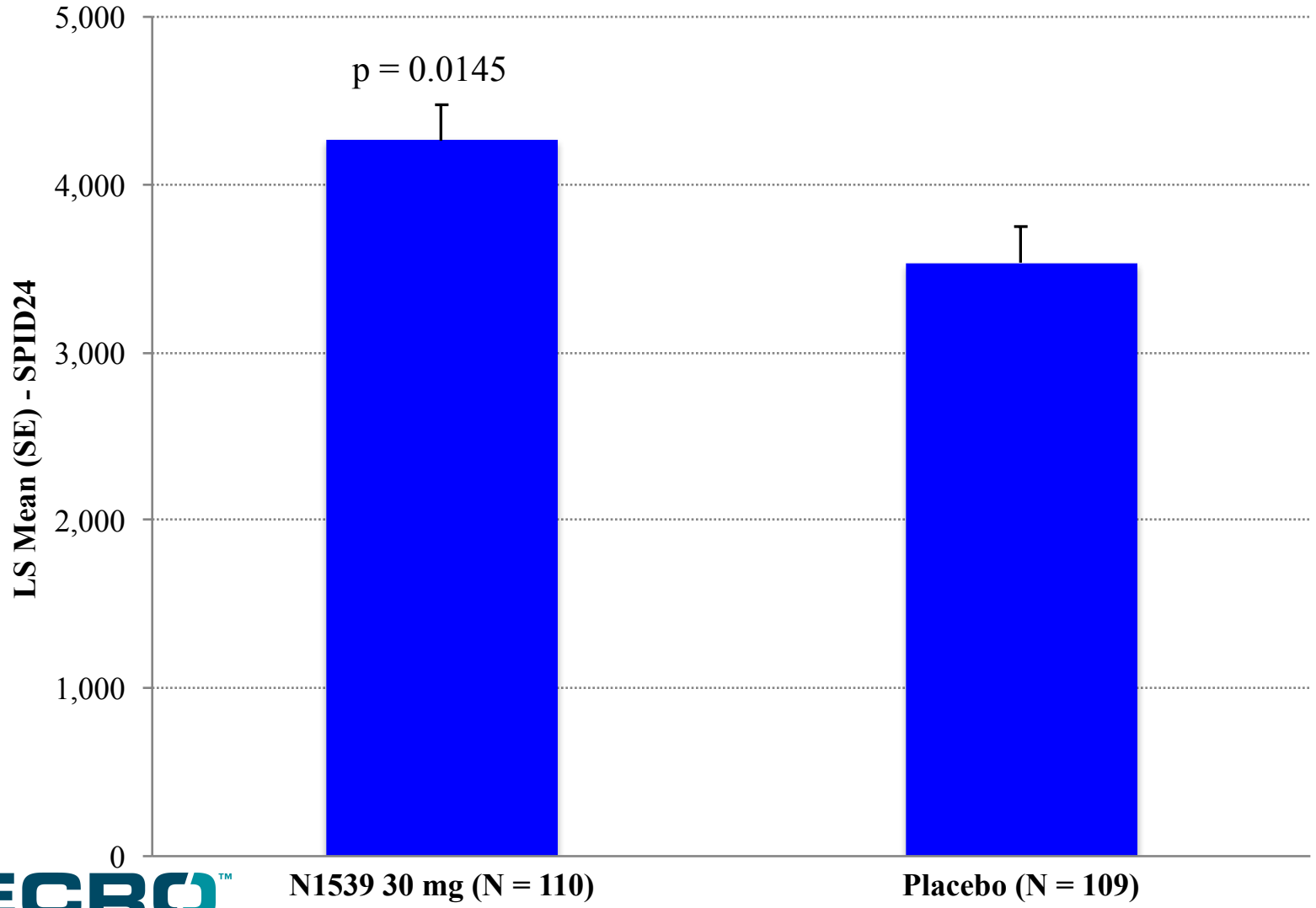
Primary Endpoint – SPID24



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Summary of Secondary Endpoints

Parameter	p-value
SPID12	0.0434
SPID48	0.0040
SPID24-48	0.0028
Number of Subjects Rescued 24-48 Hours	0.0014
Number of Times Rescued 0-24 Hours	0.0275
Number of Times Rescued 24-48 Hours	0.0009
Number of Times Rescued 0-48 Hours	0.0027
Time to Perceptible Pain Relief	0.0050
% Subjects with ≥ 30% Improvement - 24 Hours	0.0178
PGA of Pain Control at 48 hours	0.0027

SPID6, Time to Meaningful Pain Relief and First Rescue, Number of Subjects rescued 0-24 and 0-48 hours, % Subjects with ≥ 30 and ≥ 50% Improvement within 6 Hours and ≥ 50% within 24 hours, PGA of Pain Control at 24 hours were not significantly different between treatment groups.

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Adverse Events – ≥2% in the N1539 group

Preferred Term	n (%) of Subjects	
	N1539 30 mg (N=110)	Placebo (N=109)
Subjects with ≥ 1 TEAE	58 (52.7)	80 (73.4)
Nausea	30 (27.3)	41 (37.6)
Headache	13 (11.8)	18 (16.5)
Vomiting	5 (4.5)	10 (9.2)
Dizziness	4 (3.6)	10 (9.2)

**Four (4) subjects experienced Serious Adverse Events during this study. Three subjects were randomized to placebo and one to N1539.

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