Efficacy and Safety of MR-107A-02, a Novel Fast-Acting Formulation of Meloxicam, for the Treatment of Acute Moderate-to-Severe Pain Following Herniorrhaphy

Todd M. Bertoch[1], Jessica C. McCoun[1], Harold S. Minkowitz[2], Susanne Vogt[3], Scott Haughie[4], Kathleen Ocasio[5], Jeffrey P. Smith[6]

[1]CenExel JBR, Salt Lake City, UT, USA [2]Evolution Research Group, Bellaire, Texas, USA [3]Viatris, Bad Homburg, Hessen, Germany [4]Viatris/Mylan Pharma UK Ltd

[5]Viatris Inc., Canonsburg, PA, USA [6]Viatris, Morgantown, WV, USA

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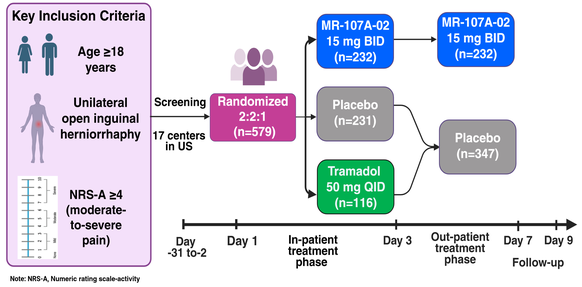
INTRODUCTION

MR-107A-02 a novel, fast-acting oral meloxicam developed by Viatris is designed to provide rapid absorption and effective non-opioid analgesia in acute pain settings. Herniorrhaphy is a FDA-approved soft tissue surgical model used for assessing analgesic efficacy and opioid-sparing potential. This phase-III study aimed to evaluate the safety and efficacy of MR-107A-02 in reducing acute pain in subjects following herniorrhaphy.

METHODS

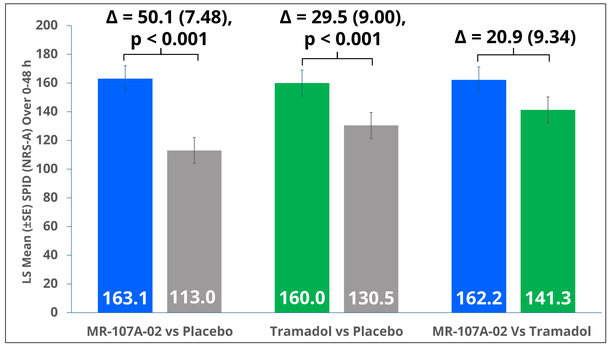
Figure 1: Study design



- Study design: Randomized, double-blind, placebo- and active-controlled, parallel group, multi-center study (Fig. 1).
- Primary efficacy endpoint: Summed pain intensity difference over 0-48 hours ($SPID_{0-48}$) based on numeric rating scale with activity (NRS-A) for MR-107A-02 vs Placebo.
- Secondary efficacy endpoint: Time to perceptible and meaningful pain relief for MR-107A-02 vs Placebo (as measured by the two-stopwatch technique).
- Safety assessments: Adverse events (AEs) were monitored.
- Statistical analyses: Least squares with 95% confidence intervals (based on ANCOVA) - to assess the difference between MR-107A-02 and placebo.

RESULTS

Figure 2: $SPID_{0-48}$ (NRS-A) in all treatment groups - Full analysis set



Note: Different values for Least Squares (LS) Means are due to different analysis of covariance (ANCOVA) models being fitted for the different comparisons (as requested by FDA).

Figure 3: NRS-A pain scores, ANCOVA by timepoint - Full analysis set

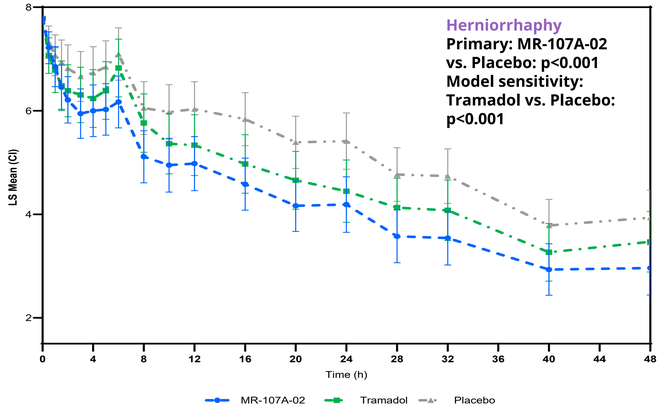
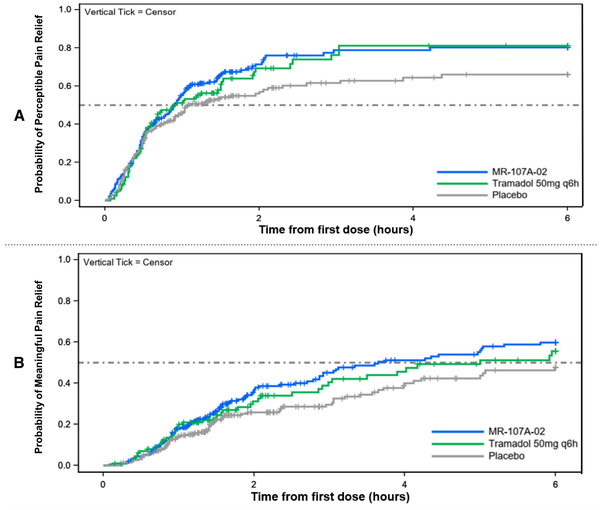


Figure 4: Time to perceptible (A) and meaningful pain relief (B) by treatment group



- Of the 579 subjects, 551 (95.1%) completed the study; 28 (4.8%) subjects discontinued.
- Patient demographics:
  - 96.3% males; 84.3% White.
  - Mean (SD): Age, 49.1(12.21) years; Weight range, 44-152 kg.
- MR-107A-02 demonstrated favorable efficacy (Fig. 2 and 3) and onset capacities (Fig. 4) compared to both placebo and tramadol.
  - Significantly higher $SPID_{0-48}$ compared with placebo.
  - Higher $SPID_{0-48}$ compared with tramadol (post-hoc analysis).
  - Reduced time to perceptible pain relief and meaningful pain relief compared to placebo.

Table 1: TEAEs in ≥ 5% subjects overall in any treatment group – Safety analysis set

Adverse events	MR-107A-02 N (%)	Placebo N (%)	Tramadol N (%)
Constipation	37 (16.1)	51 (22.5)	40 (34.8)
Nausea	22 (9.6)	23 (10.1)	22 (19.1)
Vomiting	6 (2.6)	5 (2.2)	6 (5.2)
Hyperhidrosis	18 (7.8)	17 (7.5)	9 (7.8)
Pruritus	11 (4.8)	13 (5.7)	7 (6.1)
Headache	13 (5.7)	24 (10.6)	9 (7.8)
Dizziness	17 (7.4)	17 (7.5)	17 (14.8)
Fatigue	8 (3.5)	6 (2.6)	7 (6.1)

- The most common (≥ 5%) treatment-emergent adverse events across the three treatment groups are presented in Table 1.

CONCLUSIONS

- MR-107A-02 (15 mg BID) was effective in reducing acute pain following herniorrhaphy, as demonstrated by $SPID_{0-48}$ values compared with placebo.
- MR-107A-02 showed a favorable profile compared to its opioid comparator, though the study was not powered to confirm this.
- MR-107A-02 showed a shorter time to meaningful pain relief compared to placebo and no new safety signals were identified.

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