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

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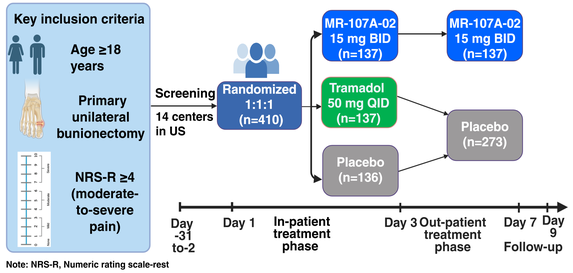
INTRODUCTION

Meloxicam demonstrates anti-inflammatory and analgesic effects. MR-107A-02 is a novel, fast-acting, oral meloxicam, developed by Viatris, designed for rapid absorption and effective non-opioid analgesia.

This phase-III study aimed to evaluate the safety and efficacy of MR-107A-02 in reducing acute pain in subjects following bunionectomy.

METHODS

Figure 1: Study design

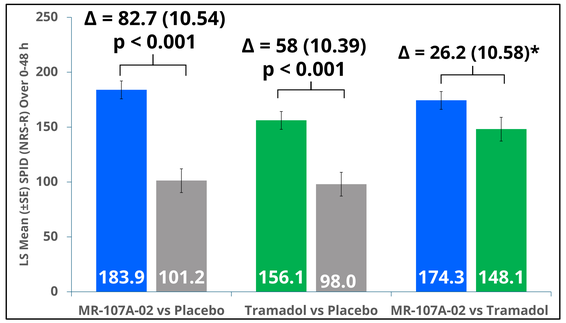


Note: NRS-R, Numeric rating scale-rest

- 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 at rest (NRS-R) 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: Monitoring of Adverse Events (AEs).
- 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-R) 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).
*Not prespecified, not part of statistical hierarchy

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

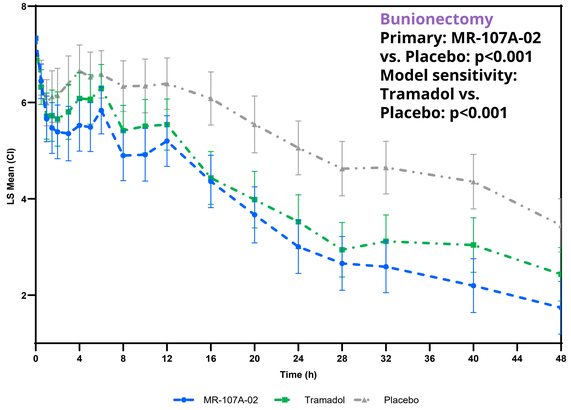
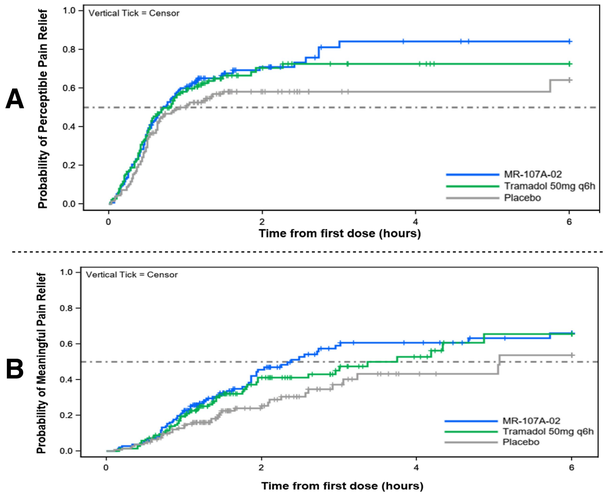


Figure 4: Time to perceptible (A) and meaningful pain relief (B) by treatment group



- Of the 410 randomized subjects, 397 (96.8%) completed the study; 13 (3.2%) discontinued with lowest number in the MR-107A-02 group (3 vs. 5 each in tramadol and placebo).
- Patient demographics:
  - 85.9% females; 60% White.
  - Mean (SD) Age, 48 (13.4) years; Weight range, 45-126 kg.
- MR-107A-02 demonstrated favorable efficacy (Fig. 2 and 3) and onset relief (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	15 (10.8)	10 (7.4)	24 (17.6)
Nausea	14 (10.1)	18 (13.3)	55 (40.4)
Diarrhea	6 (4.3)	8 (5.9)	7 (5.1)
Vomiting	7 (5.0)	0 (0.0)	24 (17.6)
Hyperhidrosis	7 (5.0)	9 (6.7)	5 (3.7)
Pruritus	10 (7.2)	11 (8.1)	21 (15.4)
Rash	7 (5.0)	2 (1.5)	5 (3.7)
Headache	13 (9.4)	9 (6.7)	14 (10.3)
Dizziness	7 (5.0)	18 (13.3)	29 (21.3)
Fatigue	7 (5.0)	12 (8.9)	8 (5.9)
C-reactive protein increased	9 (6.5)	12 (8.9)	11 (8.1)

- 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) demonstrated statistically significant reduction in acute pain following bunionectomy, as evidenced by $SPID_{0-48}$ values compared to placebo.
- MR-107A-02 showed a favorable profile compared to the 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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