Opioid Sparing Effect of MR-107A-02, A Novel Fast-Acting Meloxicam Formulation for the Treatment of Acute Moderate to Severe Pain Following Bunionectomy and Herniorrhaphy

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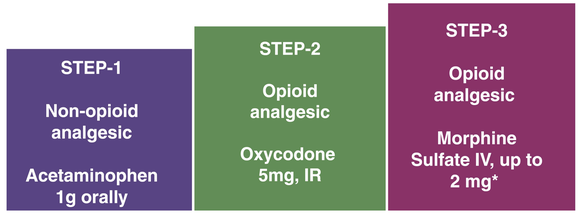
INTRODUCTION

Opioids are often used as a treatment for acute moderate-to-severe pain and have associated with certain risks. MR-107A-02 is a novel, fast-acting oral meloxicam developed by Viatris, designed to provide rapid absorption in acute pain settings. The opioid sparing effects of MR-107A-02 were evaluated using FDA-approved surgical models. These two phase-III studies aimed to assess the safety and efficacy of MR-107A-02 versus placebo and tramadol in reducing acute pain in subjects undergoing bunionectomy and herniorrhaphy.

METHODS

Figure 1: 3-Step Rescue



*Morphine sulfate was only allowed within the first 4 hours after the first dose.

- Study design: Randomized, double-blind, placebo- and active-controlled, parallel group, multi-center study.
- Primary efficacy end point: Summed pain intensity difference over 0-48 hours ($SPID_{0-48}$) based on numeric rating scale at rest (NRS-R; bunionectomy) or NRS with activity (NRS-A; herniorrhaphy) for MR-107A-02 vs placebo.
- Safety assessments were conducted throughout both the studies.
- The opioid-sparing effects of MR-107A-02,15 mg BID tablets were assessed in comparison to both placebo and tramadol, 50 mg QID tablets for the following endpoints:
  - Mean number of opioid (oxycodone and/or morphine) doses.
  - Proportion of opioid free subjects.
  - Time to first opioid use.

RESULTS

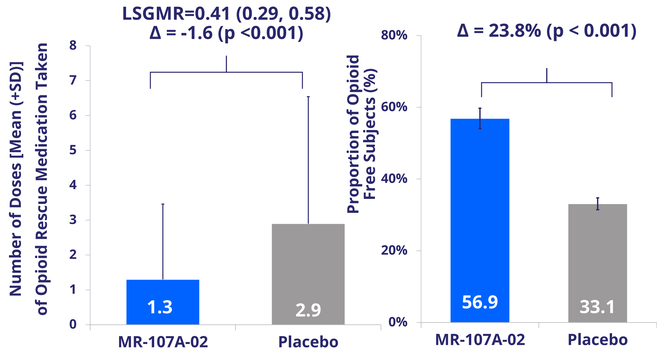
BUNIONECTOMY

- MR-107A-02 demonstrated:
  - 24% more opioid-free subjects and 59% lower mean number of opioid doses vs. placebo (Figure 2).
  - Longest median time (hours) to first opioid or any rescue medication compared to placebo and tramadol groups.
- The comparison of endpoints (the number and proportion of subjects) between MR-107A-02 versus placebo and tramadol showed:
  - Opioid rescue: 60 (43.8%) vs. 92 (67.6%) and 77 (56.2%).
  - Any rescue medication: 110 (80.3%) vs. 128 (94.1%) and 127 (92.7%) respectively.
- Serious TEAEs and TEAEs leading to death were not reported in MR-107A-02 group.
- Opioid related AEs (ORAE) were least for MR-107A-02 (16.1%) compared to placebo (16.9%) and tramadol (46.0%). The most common ORAEs are depicted in Table 1.

HERNIORRHAPHY

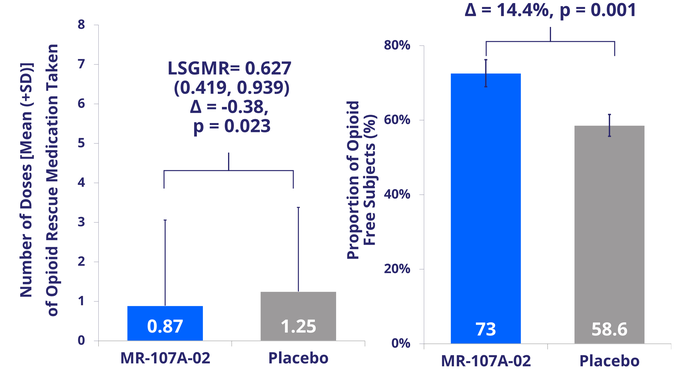
- MR-107A-02 demonstrated:
  - 14% more opioid-free subjects and 37% lower mean number of opioid doses vs. placebo (Figure 3).
  - Longest median time (hours) to first opioid or any rescue medication vs. placebo and tramadol groups.
- The comparison of endpoints (the number and proportion of subjects) between MR-107A-02 vs. placebo and tramadol exhibited:
  - Opioid rescue: 65 (28.3%) vs. 93 (41.0%) and 36 (31.3%).
  - Any rescue medication: 128 (55.7%) vs. 173 (76.2%) and 76 (66.1%) respectively.
- Serious TEAEs and TEAEs leading to death were not reported with MR-107A-02. ORAE were least in MR-107A-02 group (19.1%) compared to placebo (26.0%) and tramadol (33.9%). The most common ORAEs are depicted in Table 2.

Figure 2: Opioid sparing effect of MR-107A-02 vs placebo in bunionectomy - Full analysis set



Note: LSGMR, least squares geometric mean ratio

Figure 3: Opioid sparing effect of MR-107A-02 vs placebo in herniorrhaphy- Full analysis set



Note: LSGMR, least squares geometric mean ratio

Table 1: ORAEs in ≥ 5% of subjects in any treatment group in bunionectomy

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)
Vomiting	7 (5.0)	0 (0.0)	24 (17.6)
Pruritus	9 (6.5)	11 (8.1)	21 (15.4)
Dizziness	7 (5.0)	17 (12.6)	29 (21.3)

Table 2: ORAEs in ≥ 5% of subjects in any treatment group in herniorrhaphy

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)
Pruritus	11 (4.8)	13 (5.7)	7 (6.1)
Dizziness	17 (7.4)	15 (6.6)	15 (13.0)

CONCLUSIONS

- MR-107A-02 15 mg BID demonstrated a significant opioid-sparing effect across both studies.
- Compared to placebo, MR-107A-02 resulted in the lower mean number of opioid and/or any rescue medication doses and fewer subjects requiring such medications.
- Notably, 57% and 73% of the subjects in the MR-107A-02 group were opioid-free in the bunionectomy and herniorrhaphy studies, respectively.

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