

Symbravo® (MoSEIC™ Meloxicam and Rizatriptan) for the Acute Treatment of Migraine: Post-Hoc Composite Efficacy and Safety Endpoint Analysis of INTERCEPT and MOMENTUM

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Objective

- Further characterize the benefit-risk profile of Symbravo® using a composite endpoint comprising efficacy and safety data from 2 Phase 3 studies

Introduction

- Current acute treatment options for migraine are suboptimal for many patients, with ~70% reporting incomplete satisfaction with the available options¹, underscoring a substantial unmet need for new interventions that provide rapid, sustained response with low rates of adverse events (AEs) and decreased need for rescue medication or redosing
- Symbravo® (20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; **MxRz**) is a novel, oral, rapidly absorbed, multi-mechanistic treatment approved as an acute treatment for migraine²⁻⁵
- A key consideration in fixed-dose combination treatments is the potential for additive effects of individual components on AE rates, which can consequently influence treatment selection
- Clinical efficacy and safety outcomes are rarely integrated into single composite endpoints; however, composite measures capturing multiple aspects of benefit and risk may provide a more comprehensive assessment of overall therapeutic effect⁶⁻⁸

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Disclosures
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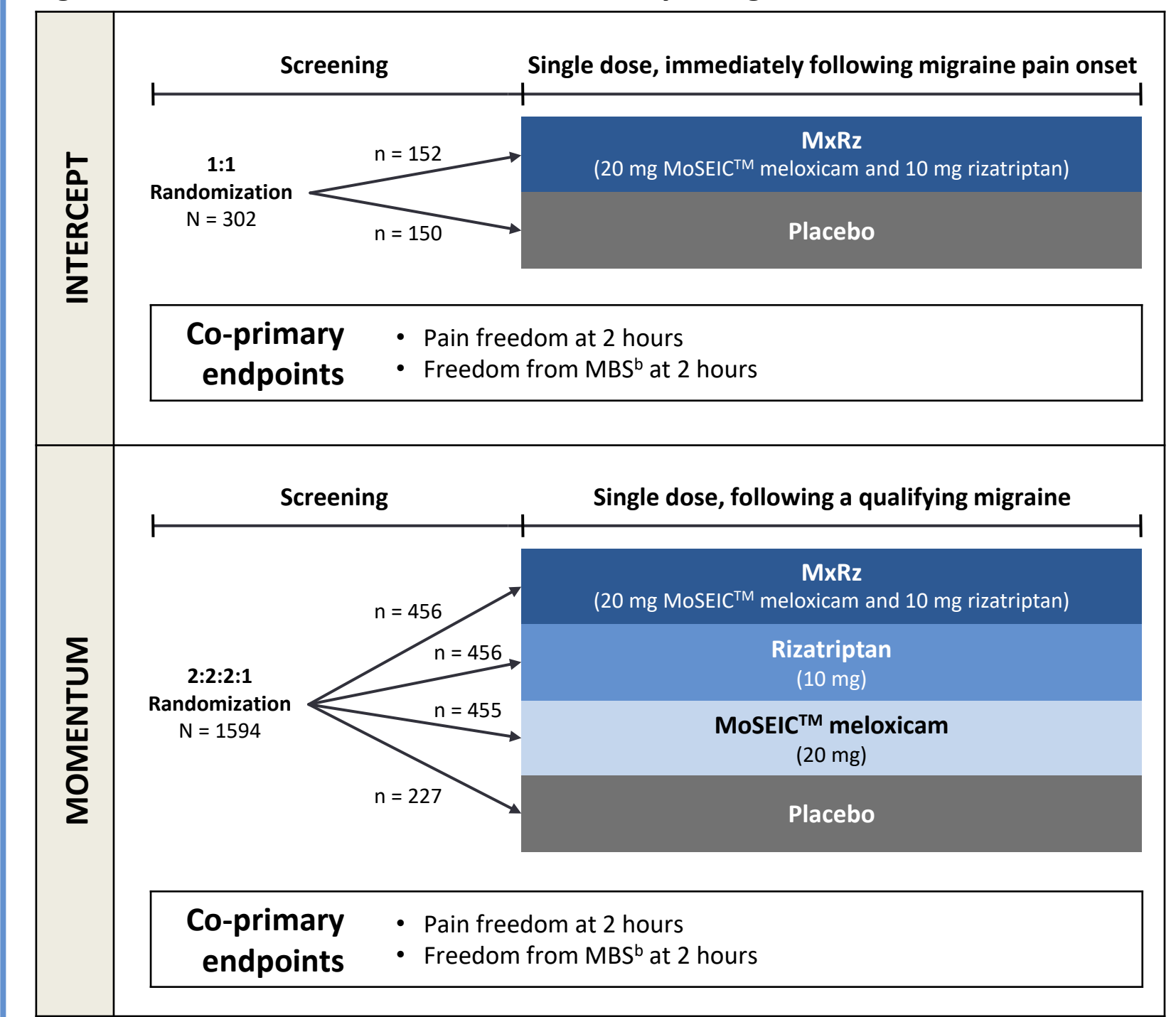


Methods

Overview of INTERCEPT and MOMENTUM

- Both INTERCEPT (NCT04163185) and MOMENTUM (NCT03896009) were randomized, double-blind, multicenter, active- (MOMENTUM) and placebo-controlled Phase 3 trials of MxRz for the acute treatment of migraine (**Figure 1**)
- No rescue medication use was allowed within 2 hours after the start of the migraine attack for either study. Participants experiencing inadequate symptom relief after 2 hours were permitted to use rescue medication⁹
- The intent-to-treat (ITT) populations comprised 302 and 1594 participants in INTERCEPT and MOMENTUM, respectively, with comparable sociodemographic and clinical characteristics across studies, despite differences in treatment timing (in INTERCEPT, treatment was initiated while pain was still mild; in MOMENTUM, participants had moderate to severe pain)

Figure 1. INTERCEPT and MOMENTUM Study Designs



⁹Permitted rescue medications included triptans, NSAIDs, antiemetics, non-NSAID analgesics, and sedatives. Barbiturates and ergotamine-containing medications were not permitted as rescue medications. ¹⁰Most bothersome symptom defined as nausea, photophobia, or phonophobia. MBS, most bothersome symptom; MxRz, 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; NSAID, non-steroidal anti-inflammatory drug.

Composite Endpoint^a Analysis

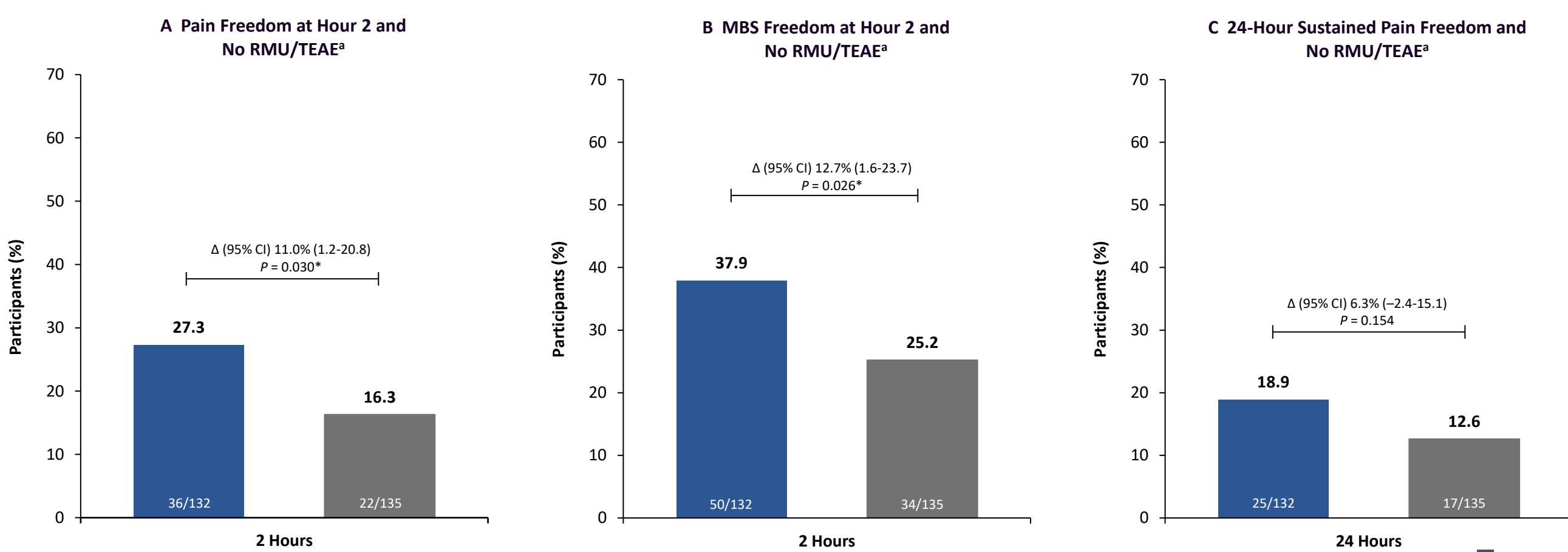
- Analyses were conducted in the ITT populations for INTERCEPT and MOMENTUM to further assess the benefit-risk of MxRz in acute treatment of migraine
- Chi-square tests were used to detect a difference between groups
- Participants with rescue medication use were censored
- As analyses were not controlled for multiplicity, all *P*-values are nominal

^aComposite endpoints were defined as:
1. 2-hour pain freedom AND no rescue medication use (RMU) at the time point OR treatment-emergent AEs (TEAEs) at any time (RMU OR TEAEs)
2. 2-hour MBS freedom AND no RMU OR TEAEs
3. Sustained 24-hour pain freedom and no RMU OR TEAEs^b
^bDefinition used for 24-hour pain freedom (pain freedom and no RMU at 24 hours) is consistent with the definition of 24-hour pain freedom from the International Headache Society.³

Results

INTERCEPT

Figure 2. Composite Efficacy and Safety Endpoints

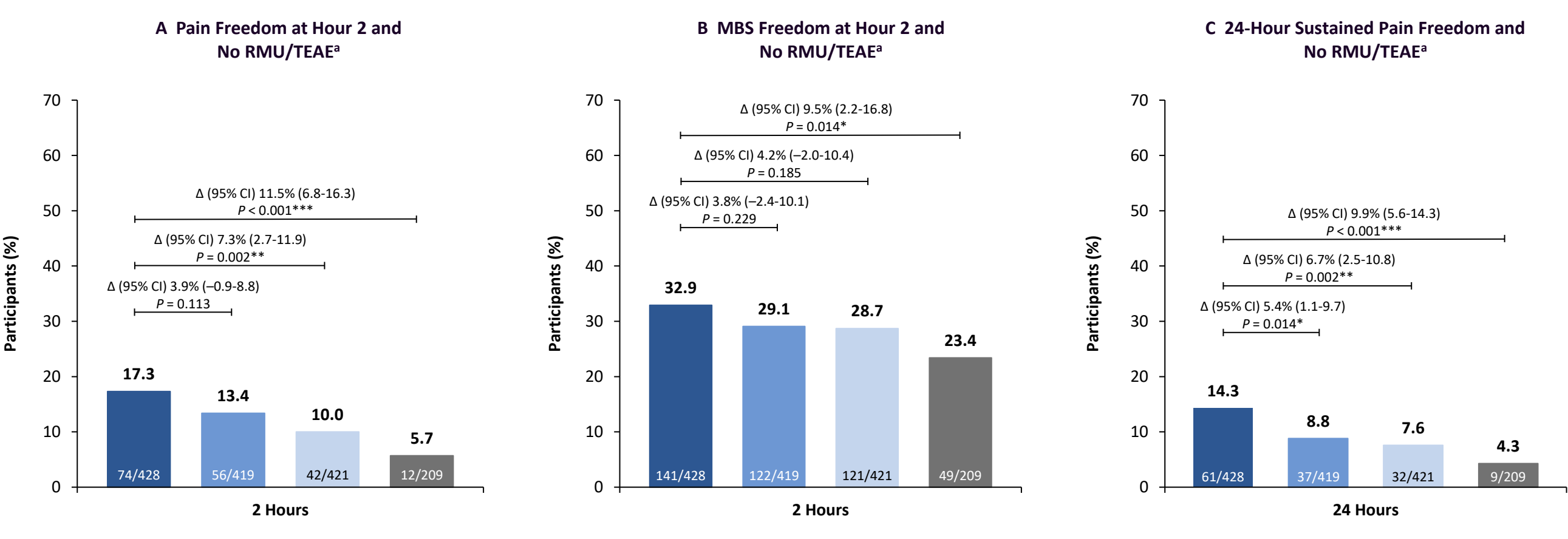


**P* < 0.05. MBS, most bothersome symptom; RMU, rescue medication use; TEAE, treatment-emergent adverse event. ^aDefined as achieving the efficacy endpoint without rescue medication use before the time point and no TEAEs at any time.

- In INTERCEPT, a greater percentage of participants treated with MxRz achieved either endpoint of pain freedom or MBS freedom with no RMU/TEAE, compared with placebo (**Figures 2A and 2B**)
- A numerically higher percentage of participants treated with MxRz achieved 24-hour sustained pain freedom with no RMU/TEAE, compared with placebo (**Figure 2C**)

MOMENTUM

Figure 3. Composite Efficacy and Safety Endpoints

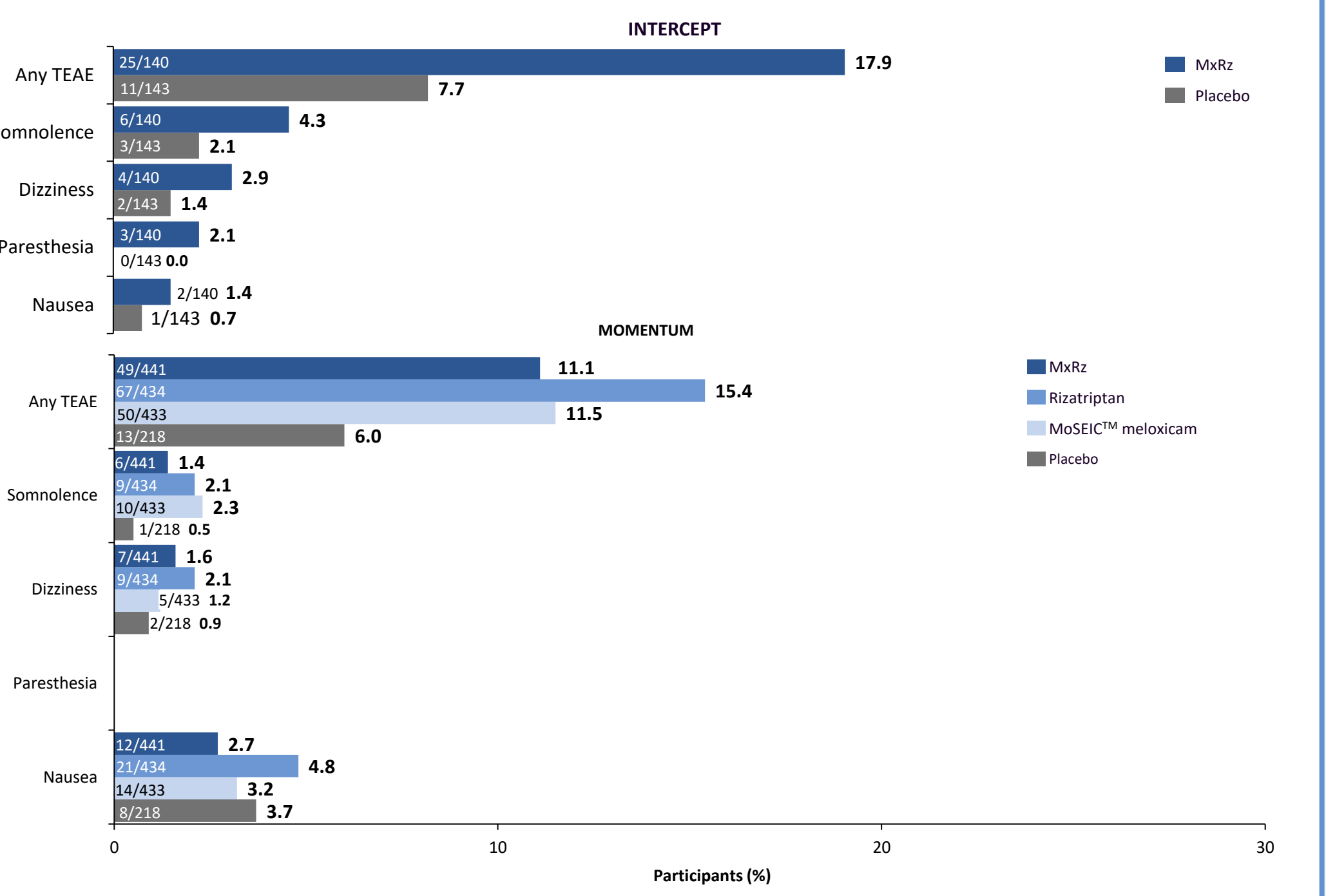


P* < 0.05; *P* < 0.01; ****P* < 0.001. MBS, most bothersome symptom; MxRz, 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; RMU, rescue medication use; TEAE, treatment-emergent adverse event. ^aDefined as achieving the efficacy endpoint without rescue medication use before the timepoint and no TEAEs at any time.

- In MOMENTUM, a greater percentage of participants treated with MxRz achieved either endpoint of pain freedom or MBS freedom with no RMU/TEAE, compared with placebo (**Figures 3A and 3B**)
- Additionally, a greater percentage of participants treated with MxRz achieved pain freedom with no RMU/TEAE, compared with MoSEIC™ meloxicam (**Figure 3A**)
- A greater percentage of participants treated with MxRz achieved 24-hour sustained pain freedom with no RMU/TEAE, compared with rizatriptan, MoSEIC™ meloxicam, or placebo (**Figure 3C**)

SAFETY

Figure 4. Treatment-Emergent and Most Common^a AEs in INTERCEPT and MOMENTUM^b



MxRz, 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; TEAE, treatment-emergent adverse event. ^a≥ 1% in any treatment group. ^bSafety analyses were based on the safety population, defined as all participants who received study drug.

- No serious AEs occurred in either the INTERCEPT or MOMENTUM studies (**Figure 4**)
- In INTERCEPT, somnolence was the only AE occurring at a rate of > 3% in the MxRz group; in MOMENTUM, no AEs occurred at a rate of > 3%
- In MOMENTUM, the rate of most AEs in the MxRz group was lower than the rates in the MoSEIC™ meloxicam and rizatriptan groups

Conclusions

- Post-hoc analyses of data from 2 Phase 3 clinical studies demonstrated that acute treatment of migraine with MxRz was associated with greater response on composite endpoints comprising efficacy and safety compared with placebo or active control
- In a fixed-dose combination treatment, there is an expectation that the individual components may have an additive effect on the AE rate. However, in our analyses, MxRz was associated with a lower rate of AEs than its individual components
 - Future analyses could include assessing the rates of AEs in responders vs non-responders
- Comparative assessments between MxRz, its components, and placebo further demonstrate the clinical value and positive benefit-risk profile of MxRz, enabling clinicians to assess relevant clinical considerations, and engage in collaborative decision making and set expectations with patients