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Long-Term Effects of Symbravo® (MoSEIC™ Meloxicam and Rizatriptan) on Headache Burden and Quality of Life: Results of the MOVEMENT Trial

Richard B. Lipton[1], Angad Chhabra[2], Todd Grinnell[2], Yang Zhao[2], Graham M.L. Eglit[2], Herriot Tabuteau[2]
[1]Department of Neurology and the Montefiore Headache Center, Albert Einstein College of Medicine, Bronx, NY, USA; [2]Axsome Therapeutics, Inc., New York, NY, USA

Key Objective

To describe the effects of long-term, open-label treatment with Symbravo® (MoSEIC™ meloxicam and rizatriptan [mMR]) on patient-reported headache-related disability, headache burden, and quality of life

Introduction

- Migraine is a chronic, debilitating neurological disorder characterized by recurrent attacks of throbbing pain, often with nausea, photophobia, and phonophobia[1]
- Approximately 70% of patients living with migraine report they are not completely satisfied with their current migraine treatments[2]
- A novel fixed-dose combination of 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan (mMR) was approved by the US Food and Drug Administration in January 2025 for the acute treatment of migraine with or without aura, based on results from the MOMENTUM (NCT03896009)[3,4] and INTERCEPT (NCT04163185)[5] phase 3 trials
  - mMR is formulated to improve the pharmacokinetics of meloxicam, as the relatively slow absorption rate of standard meloxicam limits its use for acute treatment of migraine
- The MOVEMENT (NCT04068051) trial was a long-term trial of mMR over up to 1 year in patients living with migraine[6]
- This analysis describes the patient-reported outcomes (PROs) during long-term, open-label treatment with mMR in the MOVEMENT trial

Plain Language Summary

- A new treatment called Symbravo® was recently approved by the FDA for the acute treatment of migraine
- In clinical trials, participants who took Symbravo® were more likely to have headache pain relief and relief from their most bothersome symptom within 2 hours, compared with participants who took placebo
- In this study, participants receiving open-label Symbravo® for up to 12 months experienced improvements in their migraine-related disability, headache impact, and quality of life over time

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Disclosures

Richard B. Lipton receives research support from the National Institutes of Health (NIH) and the US Food and Drug Administration (FDA). He serves on the editorial board of *Neurology*, is senior advisor to *Headache*, and is associate editor to *Cephalalgia*. He has reviewed for the National Institute on Aging (NIA) and National Institute of Neurological Disorders and Stroke (NINDS) and holds stock or options in Biohaven, CoolTech, Manistee, and NuVelBio. He serves as consultant and/or advisory board member or has received honoraria from AbbVie/Allergan, American Academy of Neurology, American Headache Society, Amgen, Axsome Therapeutics, Biohaven, Eli Lilly, GlaxoSmithKline, Lundbeck (Alder), Merck, Pernix Pharma, Pfizer, and Teva. He receives royalties from *Wolff's Headache* 7th and 8th editions, Oxford Press University, 2009, Wiley, and Informa. **Angad Chhabra**, **Todd Grinnell**, **Yang Zhao**, **Graham Eglit**, and **Herriot Tabuteau** are full-time employees of Axsome Therapeutics, Inc.

Methods

- The MOVEMENT trial was a US-based, phase 3, multicenter, open-label, long-term safety study
- Participants who completed the MOMENTUM or INTERCEPT trials could continue treatment with open-label mMR in the MOVEMENT trial (**Figure 1**)
- Eligible participants were adults who continued to experience ≥2 migraine attacks per month
- Participants could treat up to 10 migraine attacks per month at home for a maximum of 12 months, with 1 oral dose of mMR per attack

Figure 1. Study Design of MOVEMENT Trial

[a]MOMENTUM: Participants in the MOMENTUM trial were randomized 2:2:2:1 to mMR, placebo, MoSEIC™ meloxicam, or rizatriptan. [b]INTERCEPT: Participants in the INTERCEPT trial were randomized 1:1 to mMR or placebo.
DB, double-blind; EOS, end of study; mMR, 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; OL, open-label.

- PRO data were collected throughout the trial at intervals specified in **Table 1**, using the Migraine Disability Assessment (MIDAS) scale, the Headache Impact Test (HIT-6), and total score and 3 subdomains of the 14-item Migraine Specific Quality of Life Questionnaire Version 2.1 (MSQ):
  - Role function-restrictive (7 items assessing how migraine limits daily social and work-related activities)
  - Role function-preventive (4 items assessing how migraine prevents daily social and work-related activities)
  - Emotional function (3 items assessing the emotions associated with migraine)

Table 1. PRO Measures

Outcome (recall interval)	Score range	Times when collected
MIDAS (12 weeks)	0–5: little or no disability 6–10: mild disability 11–20: moderate disability ≥21: severe disability	Baseline, 3, 6, 9, and 12 months
HIT-6 (4 weeks)	36–49: little-to-no impact 50–55: moderate impact 56–59: substantial impact 60–78: severe impact	Baseline, 1, 3, 6, 9, and 12 months
MSQ (4 weeks)	0–100 for total score and subdomain scores <40: extremely impaired 40–54: severely impaired 55–74: moderately impaired 75–84: mildly impaired 85–100: not/minimally impaired[a]	Baseline, 1, 3, 6, 9, and 12 months

- Mean (95% confidence interval [CI]) change from baseline and the percentage of participants achieving a minimal clinically important difference (MCID) or minimal clinically important change (MCIC) from baseline were examined at each timepoint
  - MIDAS MCIC: ≥4.5 points change[8]
  - HIT-6 MCID: ≥5 points change[9]
  - MSQ MCID for role function-restrictive, role function-preventive, and emotional function subdomains: ≥5, 5, and 8 points change, respectively[10]

Limitations

- This study had a single-arm, open-label design, and thus lacks a contemporaneous control group
- Many participants were exposed to mMR for less than 12 months; however, this was primarily due to closing of the study after meeting safety exposure goals. Though the total discontinuation rate was 80.5%, 57.1% were discontinued due to the study closing

Results

Participant Baseline Characteristics

Table 2. Demographics and Baseline Characteristics

	mMR ITT population (N=704)
Age, y, mean (SD)	42.0 (11.0)
Female, n (%)	578 (82.1)
Race, n (%)	
White	542 (77.0)
Black	132 (18.8)
Asian	12 (1.7)
Other/multiple	18 (2.6)
Migraine classification, n (%)	
Without aura	438 (62.2)
With aura	136 (19.3)
With and without aura	130 (18.5)
mTOQ-4 score, n (%)	
Maximum treatment efficacy (8)	53 (7.5)
Moderate treatment efficacy (4–7)	388 (55.1)
Poor treatment efficacy (1–3)	211 (30.0)
Very poor treatment efficacy (0)	52 (7.4)
Time since migraine diagnosis, y, mean (SD)	18.2 (11.7)
Obesity (BMI ≥30 kg/m²), n (%)	323 (45.9)
Baseline MIDAS total score, median (IQR)	17.0 (11.0–28.0)
Baseline HIT-6 total score, median (IQR)	64.0 (61.0–67.0)
Baseline MSQ score, median (IQR)	
Total	54.0 (42.8–62.0)
Role function-restrictive	51.4 (34.3–60.0)
Role function-preventive	65.0 (48.8–80.0)
Emotional function	60.0 (40.0–80.0)

- The intent-to-treat population included a total of 704 participants (**Table 2**)
- Participants had a mean age of 42 years, and were mostly female (82%) and White (77%)
- Mean baseline MIDAS score was 22.5 (indicating severe disability), HIT-6 score was 64.1 (indicating severe impact), and MSQ domains of role function-restrictive, role function-preventive, and emotional function were 47.6, 62.2, and 59.0, respectively (indicating moderate to severe impairment)

BMI, body mass index; HIT-6, Headache Impact Test; IQR, interquartile range; ITT, intent-to-treat; MIDAS, Migraine Disability Assessment; mMR, 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; MSQ, 14-item Migraine Specific Quality of Life Questionnaire Version 2.1; mTOQ-4, Migraine Treatment Optimization Questionnaire-4.

Safety

Table 3. Treatment-Emergent Adverse Events

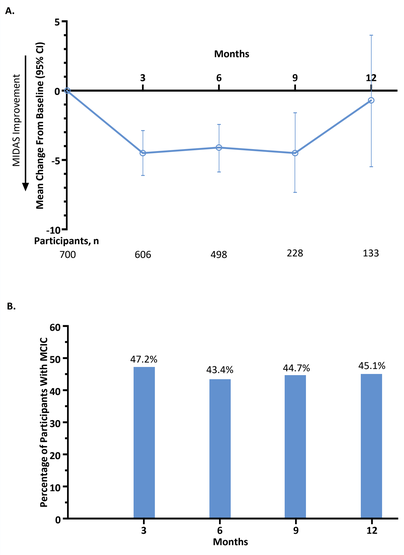
	mMR safety population (N=706)
Participants with any TEAEs, n (%)[a]	293 (41.5)
Nausea	40 (5.7)
Vomiting	33 (4.7)
Dizziness	22 (3.1)
Somnolence	20 (2.8)
Diarrhea	16 (2.3)
Upper respiratory tract infection	14 (2.0)
Participants with serious TEAEs, n (%)[b]	8 (1.1)
Participants with TEAEs that led to withdrawal from study, n (%)[c]	13 (1.8)
Nausea	3 (0.4)
Vomiting	2 (0.3)
Participants with treatment-related TEAEs, n (%)[a,d]	118 (16.7)
Nausea	32 (4.5)
Dizziness	19 (2.7)
Somnolence	19 (2.7)
Vomiting	18 (2.5)
Participants with TEAEs that resulted in death, n (%)	0

- mMR was well tolerated throughout the 12-month period and had a safety profile generally consistent with that previously reported in short-term controlled trials
- The most common adverse events (AEs) were nausea (5.7%), vomiting (4.7%), dizziness (3.1%), somnolence (2.8%), diarrhea (2.3%), and upper respiratory tract infection (2%; **Table 3**)
- The rate of discontinuation due to TEAEs was 1.8%

[a]In ≥2% of participants. [b]One additional non-treatment-emergent serious AE occurred. [c]In ≥1 participant. [d]Relatedness was assessed by the investigator.
AE, adverse event; mMR, 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan; TEAE, treatment-emergent adverse event.

PRO Results

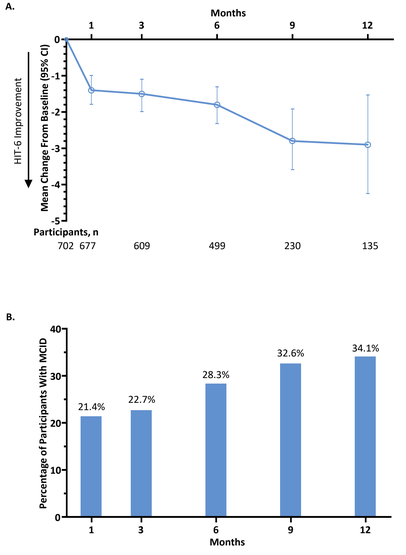
Figure 2. Change in MIDAS Total Scores Over Time (A) and Percentage of Participants Achieving MCIC (B)



MCIC threshold was 4.5 points change.
MCIC, minimal clinically important change; MIDAS, Migraine Disability Assessment.

- MIDAS total scores improved from baseline up to the 12-month study visit (**Figure 2A**)
- At the early termination visit, the average (95% CI) change in MIDAS was -5.3 (-7.11, -3.41)
- The percentage of participants who reached an MCIC in MIDAS was above 40% at each timepoint (**Figure 2B**)

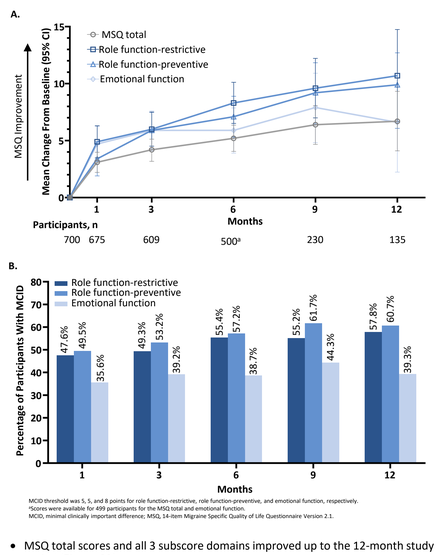
Figure 3. Change in HIT-6 Total Scores Over Time (A) and Percentage of Participants Achieving MCID (B)



MCID threshold was 5 points change.
HIT-6, Headache Impact Test; MCID, minimal clinically important difference.

- HIT-6 total scores also improved up to the 12-month study period (**Figure 3A**)
- At the early termination visit, the average (95% CI) change was -2.4 (-3.01, -1.88) for HIT-6
- The percentage of participants reaching an MCID in HIT-6 score increased from 21.4% at Month 1 to 34.1% at Month 12 (**Figure 3B**)

Figure 4. Change in MSQ Total Scores and Role Function-Restrictive, Role Function-Preventive, and Emotional Function Subscores Over Time (A) and Percentage of Participants Achieving MCID (B)



MCID threshold was 5, 5, and 8 points for role function-restrictive, role function-preventive, and emotional function, respectively.
[a]Scores were available for 499 participants for the MSQ total and emotional function.
MCID, minimal clinically important difference; MSQ, 14-item Migraine Specific Quality of Life Questionnaire Version 2.1.

- MSQ total scores and all 3 subscore domains improved up to the 12-month study period (**Figure 4A**)
- At the early termination visit, the average (95% CI) change in MSQ total score was 5.8 (4.52–7.06), role function-restrictive was 9.4 (7.40–11.35), role function-preventive was 7.5 (5.51–9.44), and emotional function was 6.7 (4.49–8.90)
- For all 3 subscores, the percentage of participants who reached an MCID increased up to the 12 months (**Figure 4B**):
  - From 47.6% at Month 1 to 57.8% at Month 12 for role function-restrictive
  - From 49.5% at Month 1 to 60.7% at Month 12 for role function-preventive
  - From 35.6% at Month 1 to 39.3% at Month 12 for emotional function

Conclusions

- Over an up to 12-month period, treatment with open-label, fixed-dose combination of 20 mg MoSEIC™ meloxicam and 10 mg rizatriptan (Symbravo®) was associated with improvement in quality of life and reduction in headache-related disability and headache impact
  - Despite migraine treatment being for acute episodes, the observed improvements on these PROs over the open-label extension period demonstrate the cumulative impact that successful treatment has on patient overall well-being
- Over the up to 12-month treatment period, mMR was well tolerated and the safety profile was consistent with that previously reported in short-term controlled trials