

# AZR-MD-001 Ophthalmic Ointment Opens Meibomian Glands, Improves Meibum Quality, and Improves Tear Film Stability Over 3 Months of Dosing in Patients With Contact Lens Discomfort

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## INTRODUCTION

- Contact lens discomfort (CLD) is a common problem for contact lens wearers (occurring at reported rates of 31%–58%)<sup>1</sup> and practitioners due to high discontinuation rates.
  - CLD is defined as “a condition characterized by episodic or persistent adverse ocular sensations related to contact lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation of contact lens wear.”<sup>2</sup>
- Some individuals with CLD also have changes to the morphology and function of meibomian glands, including gland obstruction and quality of secretion.<sup>1</sup>
- AZR-MD-001 is an ophthalmic keratolytic, keratostatic, and lipogenic ointment containing selenium sulfide shown to improve signs and symptoms of meibomian gland dysfunction (MGD).<sup>3</sup>
- The study objective was to evaluate whether AZR-MD-001 can open meibomian glands in patients with CLD and signs of MGD who continue to wear contact lenses.

## DEMOGRAPHICS

- All participants reported wearing soft contact lenses, with the majority using daily disposable lenses (49/67, 73%). Additional baseline characteristics are presented (Table 1).

TABLE 1. DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PARTICIPANTS

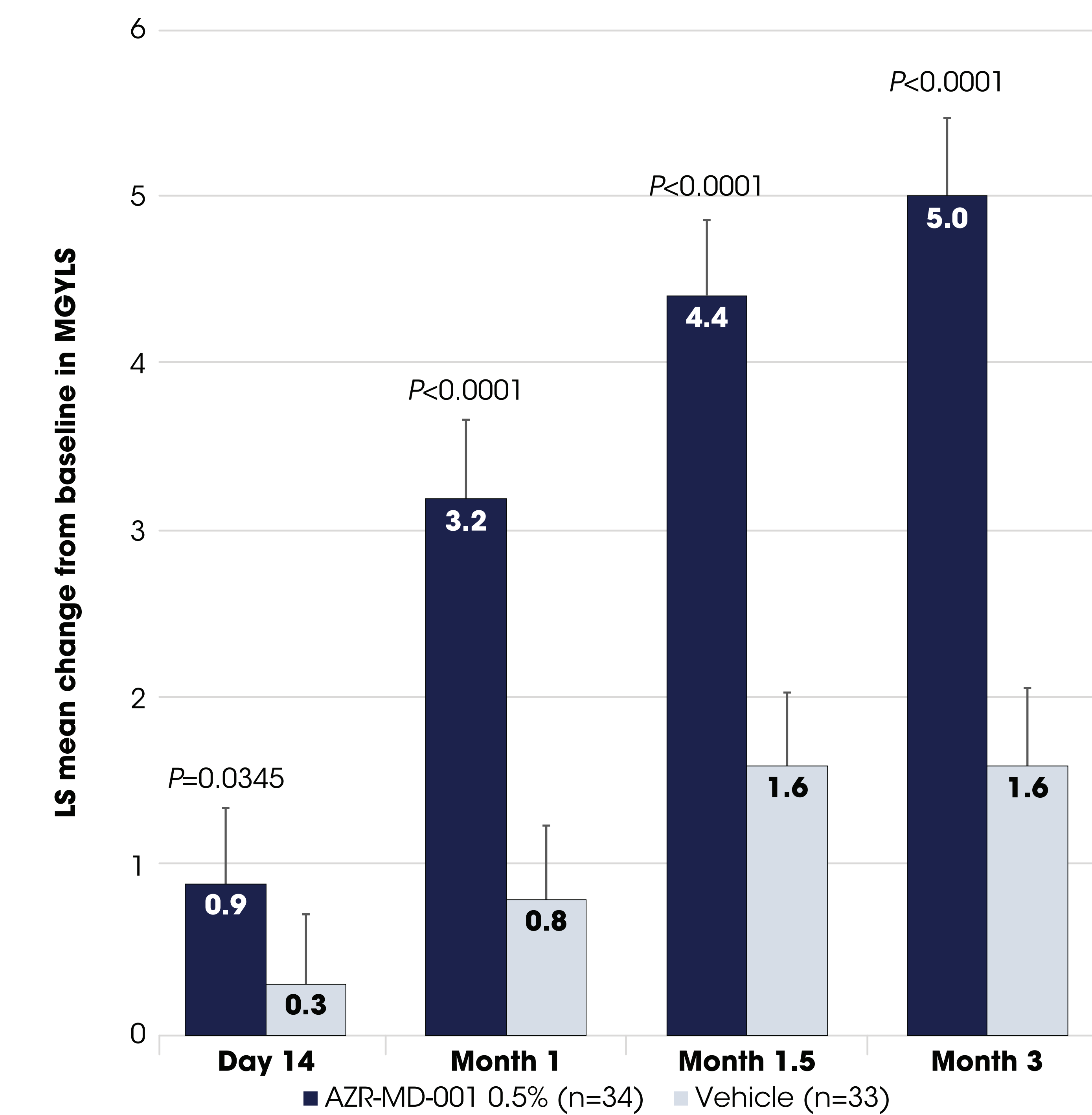
		AZR-MD-001 (n=34)	VEHICLE (n=33)	OVERALL (N=67)
Age (years)	Mean (SD)	46.7 (12.8)	49.4 (14.3)	48.0 (13.5)
	Median (min, max)	47.5 (18, 76)	51 (18, 72)	48 (18, 76)
Sex, n (%)	Female	29 (85)	26 (79)	55 (82)
	Male	5 (15)	7 (21)	12 (18)
Race, n (%)	White	26 (76)	26 (79)	52 (78)
	Asian	8 (24)	7 (21)	15 (22)
Number of MGYSL*	Mean (SD)	2.8 (0.8)	3.0 (0.6)	2.9 (0.7)
MGS score*	Mean (SD)	8.4 (1.7)	8.7 (1.6)	8.6 (1.6)
TBUT (seconds)*	Mean (SD)	6.3 (2.2)	5.5 (1.6)	5.9 (1.9)
CWT (hours)*	Mean (SD)	6.6 (2.4)	5.4 (2.4)	6.0 (2.4)

Percentages may not add to 100% due to rounding. Characteristics captured at the baseline visit and reported for the safety population (all participants who were dispensed study medication), unless specified otherwise. \*Reported for ITT population (all randomized patients). CWT, comfortable wear time; MGS, Meibomian Gland Secretion; MGYSL, Meibomian Glands Yielding Liquid Secretion; SD, standard deviation; TBUT, tear break-up time.

## RESULTS

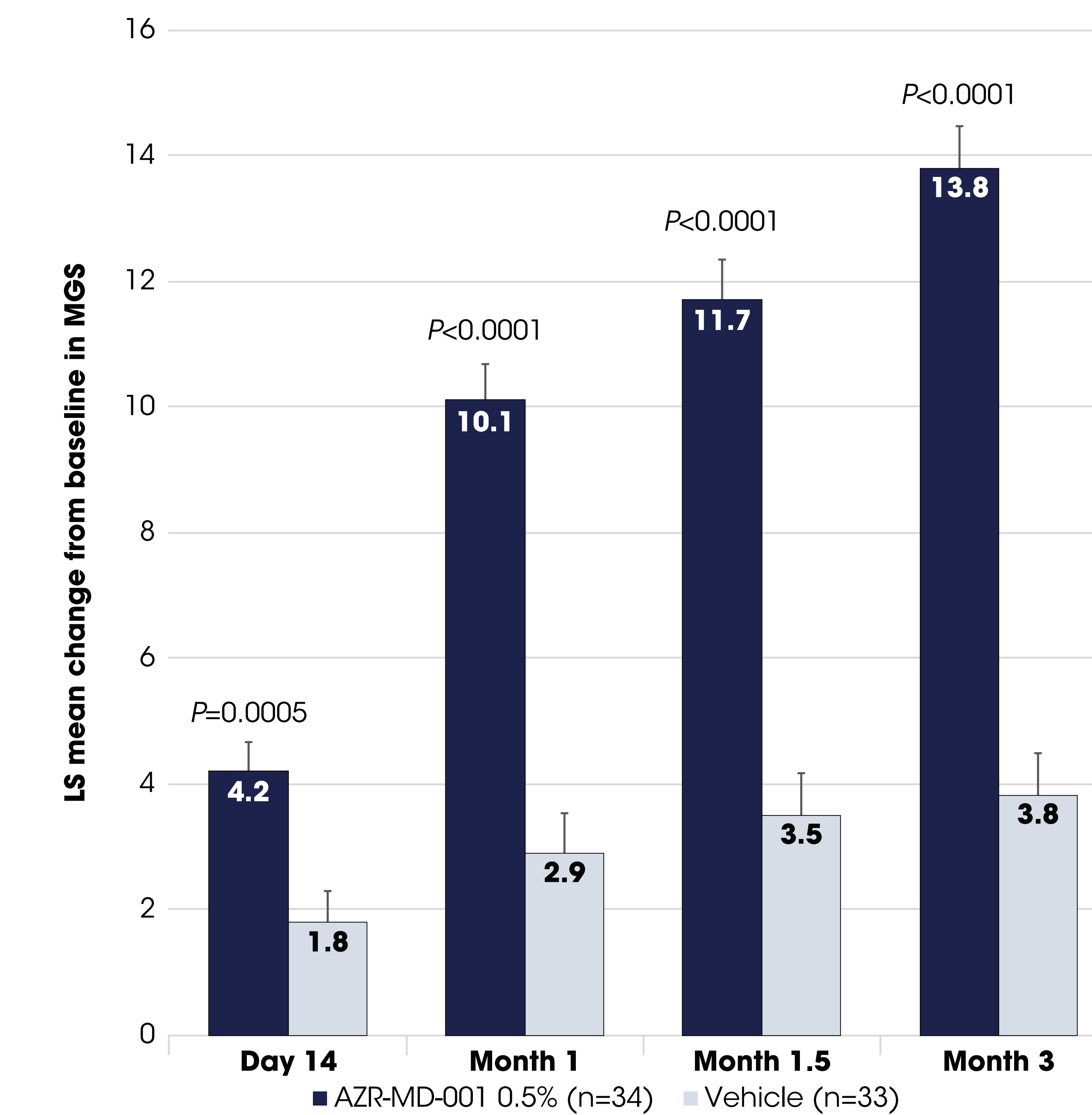
- AZR-MD-001 0.5% met the primary sign endpoint, resulting in statistically significant increases in the number of MGYSL versus vehicle at Month 3 (Figure 1), and showed significant improvement versus baseline for CLD symptoms (CLDEQ-8 total score: -8.4 [1.85],  $P < 0.0001$ ; CLDEQ-8 fluctuating vision item scores: -2.0 [0.55],  $P = 0.0011$ ) but not versus vehicle at Month 3 (data not shown).
- Improvements over vehicle were seen as early as Day 14, and throughout Month 3, in the number of open glands (Figure 1) and meibum secretion quality (Figure 2).
- AZR-MD-001 improved tear film stability versus vehicle from Month 1 to Month 3 (Figure 3).
- Please see other ARVO 2024 posters for additional efficacy results (2971 – A0130; 2677 – B0513, 2669 – B0505).

FIGURE 1. MEAN CHANGE FROM BASELINE IN NUMBER OF MGYSL OVER TIME (ITT POPULATION)



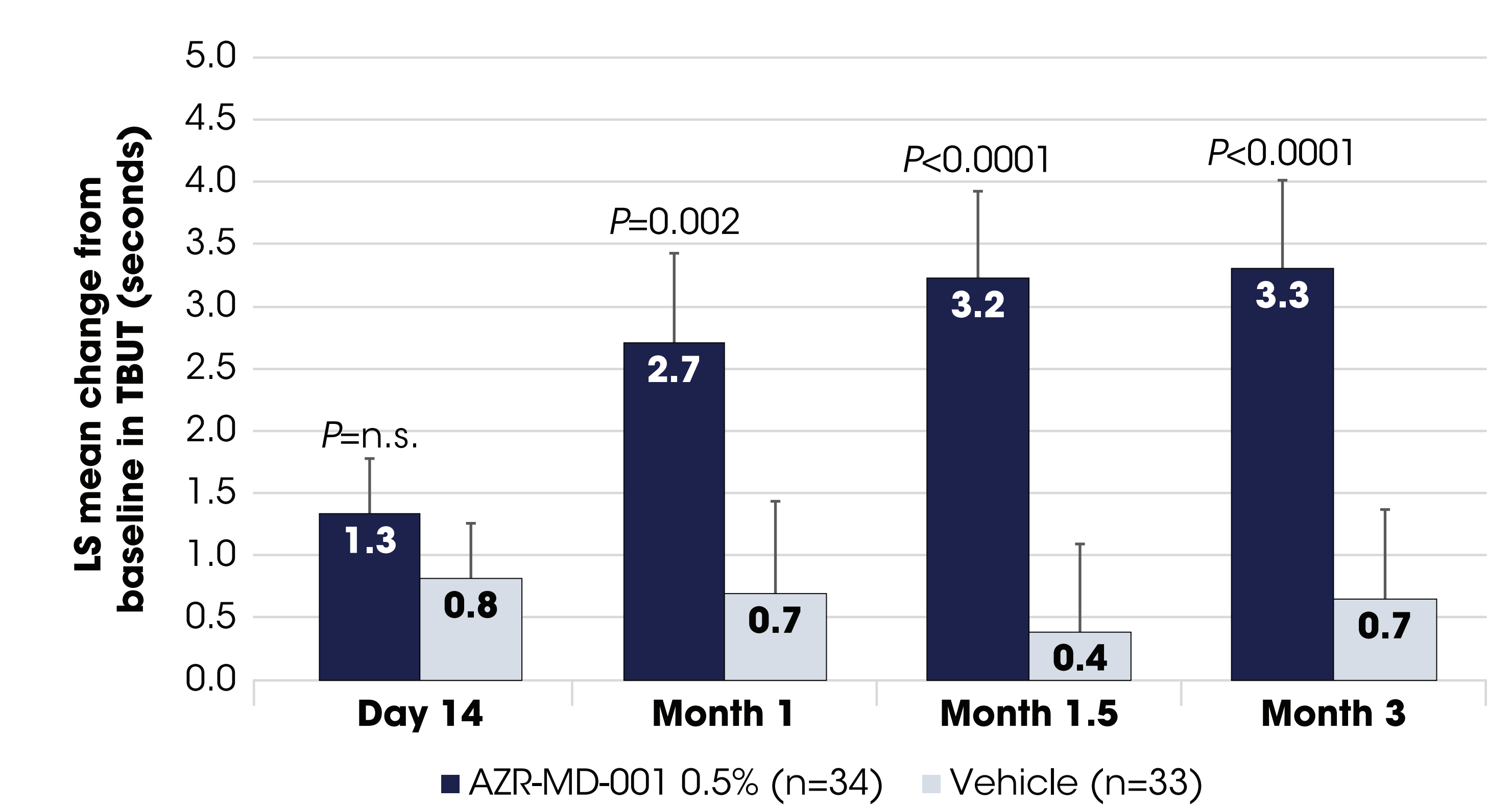
P-values completed using least squares mean difference from baseline compared to vehicle. ITT, intent-to-treat (all randomized patients); LS, least squares; MGYSL, Meibomian Glands Yielding Liquid Secretion.

FIGURE 2. MEAN CHANGE FROM BASELINE IN MGS SCORE OVER TIME (ITT POPULATION)



P-values completed using least squares mean difference from baseline compared to vehicle. ITT, intent-to-treat (all randomized patients); LS, least squares; MGS, Meibomian Gland Secretion.

FIGURE 3. MEAN CHANGE FROM BASELINE IN TBUT OVER TIME (ITT POPULATION)



P-values completed using LS mean difference from baseline compared to vehicle. ITT, intent-to-treat (all randomized patients); LS, least squares; n.s., not significant; TBUT, tear break-up time.

- All TEAEs were mild to moderate in severity, transient upon installation, did not lead to treatment discontinuation or disrupted normal routine, and resolved with continued dosing in about a month.
- The only TEAEs to occur in more than one patient were eye irritation and conjunctival hyperemia, all events of which were considered related to study drug (Table 2).

TABLE 2. SUMMARY OF TEAEs (SAFETY POPULATION)

Patients, n (%)	AZR-MD-001 0.5% (N=34)	VEHICLE (N=33)
Any TEAE	23 (67.6%)	3 (9.1%)
Any ophthalmic TEAE (in either eye)	23 (67.6%)	1 (3.0%)
TEAEs reported in ≥5% of patients in any arm <sup>†</sup>		
Eye irritation	21 (61.8%)	0
Conjunctival hyperemia	2 (5.9%)	0
Any related TEAE*	23 (67.6%)	0

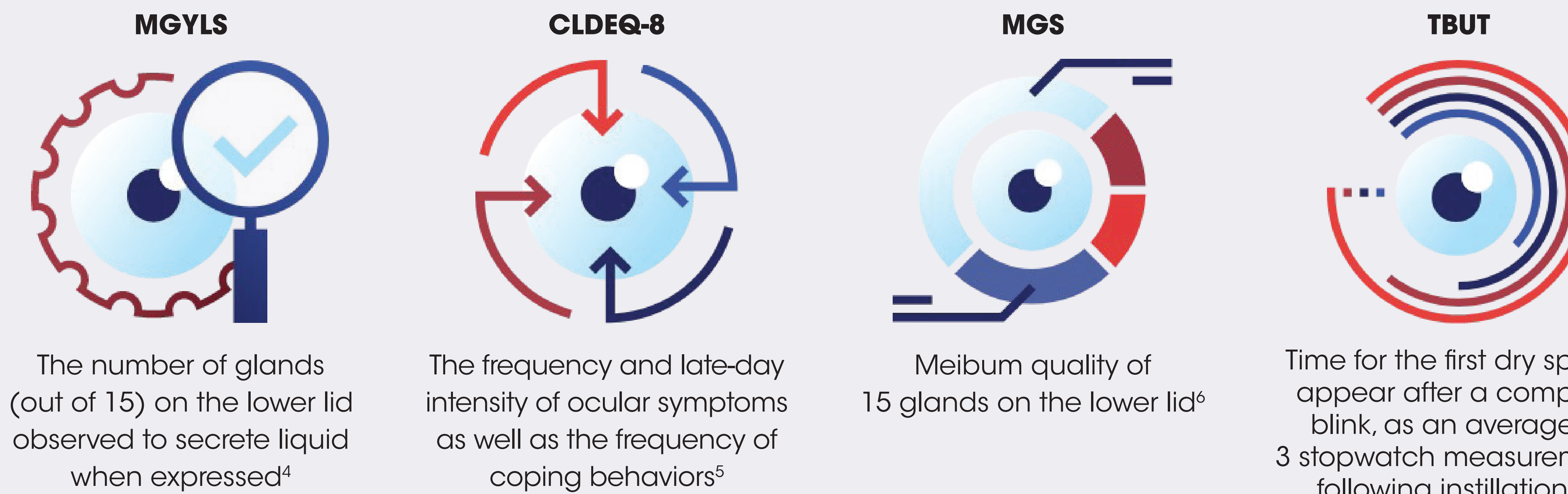
Safety population included all participants who were dispensed study medication. \*All events with AZR-MD-001 were considered possibly, probably, or very likely/certainly related to study drug in the opinion of the investigator. TEAE, treatment-emergent adverse event.

## CONCLUSIONS

- AZR-MD-001 significantly improved signs of MGD and tear film stability in CLD beginning as early as 14 days (4 applications) with improvement to 3 months compared to vehicle.
- AZR-MD-001 was safe and well tolerated over 3 months.

## METHODS

- Study design:** Phase 2, multicenter, parallel-group, double-masked, vehicle-controlled, randomized trial (NCT05548491)
- Eligible patients:** Adults (≥18 years) who had evidence of MGD (based on a meibomian gland secretion [MGS] score of ≤12 for 15 glands of the lower lid) in both eyes at baseline; had a history of wearing soft contact lenses for ≥6 months before the baseline visit; self-reported history of contact lens dryness/intolerance in the 6 months preceding baseline; and had a Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score of >12 at baseline
  - Contact lenses were to be used during the study and were to be removed 15 minutes before dosing and for scheduled visits.
- Treatment:** Patients randomized (1:1) to AZR-MD-001 0.5% or vehicle applied twice weekly to the lower eyelid after contact lens removal and just before bedtime
  - No conventional treatments allowed during the study
- 6 scheduled visits:** Screening (Day -2 to -14), randomization/baseline (Day 0), Day 14, Month 1, Month 1.5, and Month 3
- Primary efficacy endpoints:** Hierarchical order: Change from baseline to Month 3 versus vehicle in (1) Meibomian Gland Yielding Liquid Secretion (MGYSL), (2) CLDEQ-8 total score, and (3) CLDEQ-8 fluctuating vision items
- Secondary efficacy endpoints:** Change from baseline versus vehicle in MGS score (key secondary) and in tear break-up time (TBUT; additional secondary)
- Safety and tolerability:** Assessed by the nature, incidence, and severity of treatment-emergent adverse events (TEAEs)
- Change from baseline analysis:** Evaluated using an analysis of covariance model with continuous baseline score as a covariate and treatment and baseline MGS score category (<6 or ≥6 and ≤12) as factors



## Contact

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## References

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## Disclosures

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