

# AZR-MD-001 Improves Corneal and Conjunctival Damage in Patients With CLD and MGD

Charles Bosworth,<sup>1</sup> Mark Hinds,<sup>2</sup> Eric Kassel,<sup>1</sup> Yair Alster<sup>1</sup>

<sup>1</sup>Azura Ophthalmics Ltd, Tel Aviv, Israel; <sup>2</sup>Ophthalmic Trials Australia, Brisbane, Australia

This phase 2 study was sponsored by Azura Ophthalmics Ltd

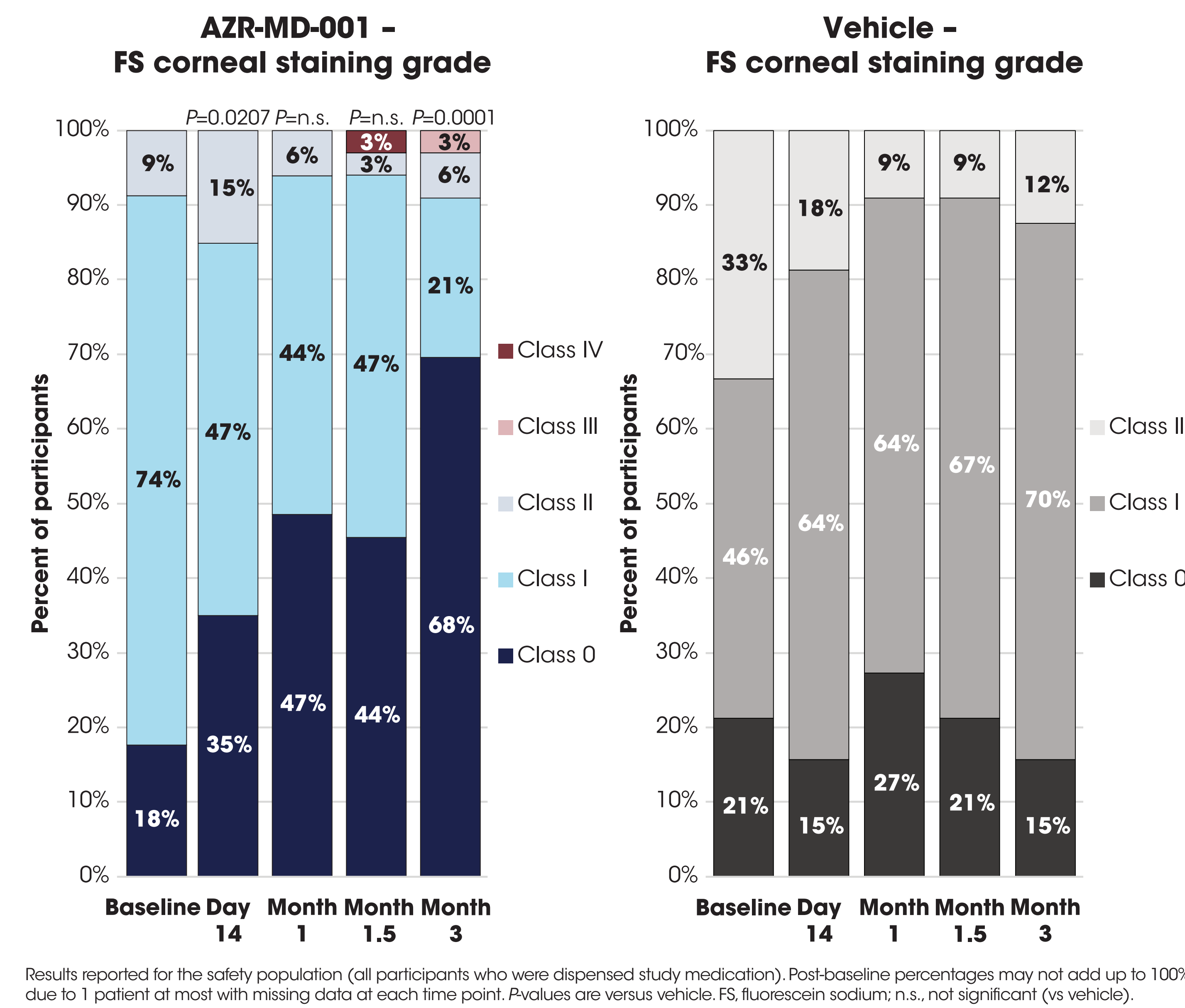
## INTRODUCTION

- Contact lens discomfort (CLD) is characterized by episodic or persistent adverse ocular sensations related to contact lens (CL) wear, either with or without visual disturbance, resulting from reduced compatibility between the CL and the ocular environment, which can lead to decreased wearing time and discontinuation of CL wear.<sup>1</sup>
- 12-51% of CL wearers are estimated to discontinue CL use due to CLD,<sup>2</sup> and 31-58% of CL wearers are considered symptomatic.<sup>3</sup>
- AZR-MD-001 is an ophthalmic keratolytic, keratostatic, and lipogenic ointment containing selenium sulfide, which can improve both the signs and symptoms of meibomian gland dysfunction (MGD).<sup>4</sup>
- This study evaluated the effect of treating the meibomian glands with AZR-MD-001 on the ocular surface in patients with CLD who have signs of MGD, who continue to challenge their ocular surface with persistent CL use.

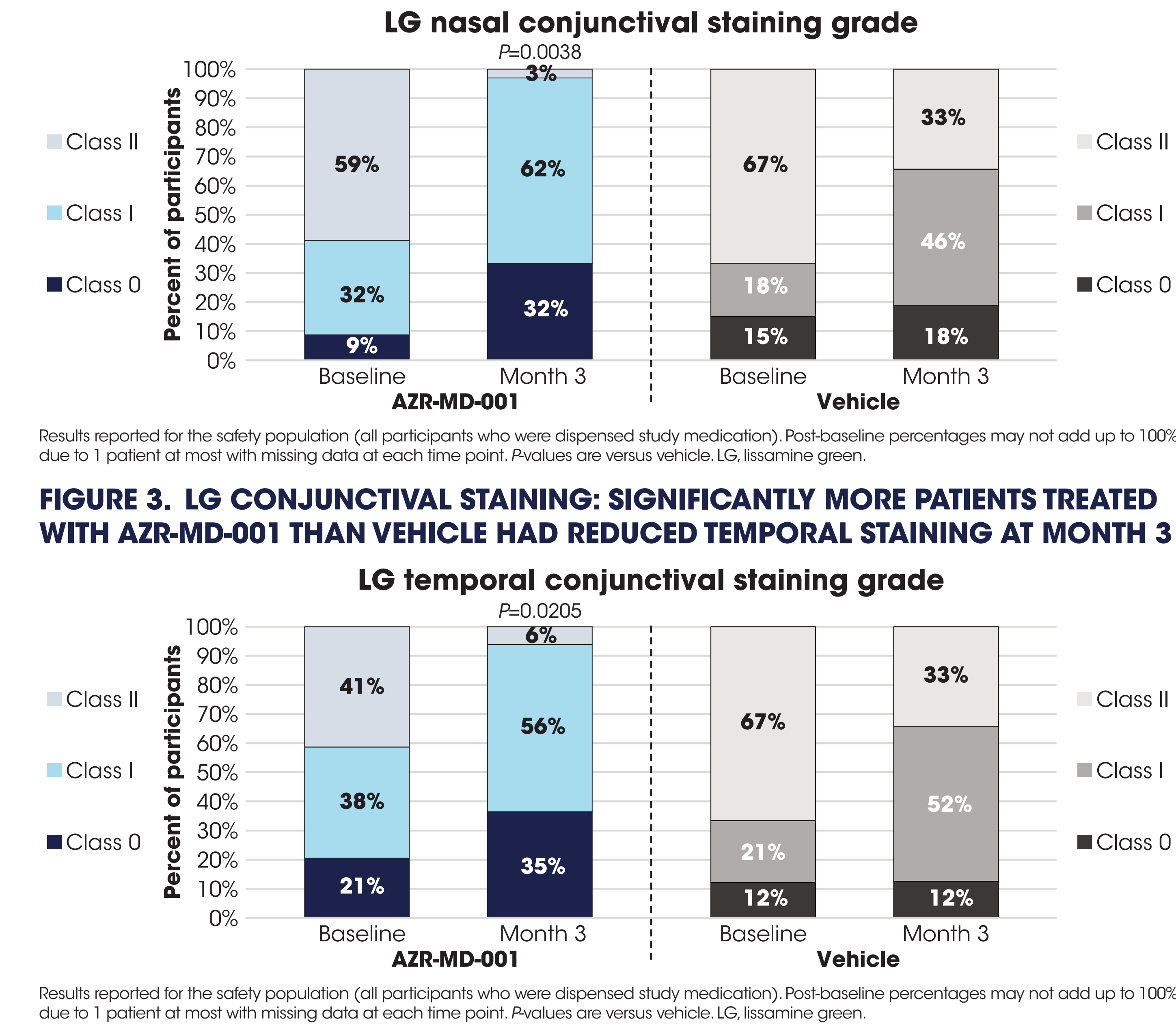
## RESULTS

- AZR-MD-001 0.5% met the primary endpoint for MGYLS change from baseline to Month 3 versus vehicle and did not meet statistical significance for CLDEQ-8 change from baseline to Month 3 versus vehicle for total or fluctuating vision item scores. (Please see poster 6584 - B0271 for primary efficacy results.)
- The percentage of patients with reduced corneal staining increased over time with AZR-MD-001 treatment, with a near four-fold increase from baseline to Month 3 in patients with no staining (from 18% to 68%); at Month 3, 67% of patients treated with AZR-MD-001 had a score of 0 compared to 15% of patients treated with vehicle (Figure 1).
- Treatment with AZR-MD-001 was associated with a significant downward shift in LG nasal conjunctival staining grade at Month 3 compared to vehicle, with 32% of participants having a score of 0 versus 18% with vehicle and with a near four-fold increase from baseline (18%) to Month 3 (32%) with AZR-MD-001 in patients with no staining (Figure 2).
- A significant downward shift in LG temporal conjunctival staining grade was observed with AZR-MD-001 compared to vehicle at Month 3, with 35% of patients treated with AZR-MD-001 having a score of 0 versus 12% of patients receiving vehicle and with a near two-fold increase from baseline (18%) to Month 3 (35%) with AZR-MD-001 in patients with no staining (Figure 3).
- Compared to vehicle, AZR-MD-001 significantly increased the amount of time patients could comfortably wear their CL (3.2 h for AZR-MD-001 versus 0.05 h for vehicle, P<0.0001) (Figure 4).
- Please see other ARVO 2024 posters for additional efficacy results (2971 - A0130; 2677 - B0513).

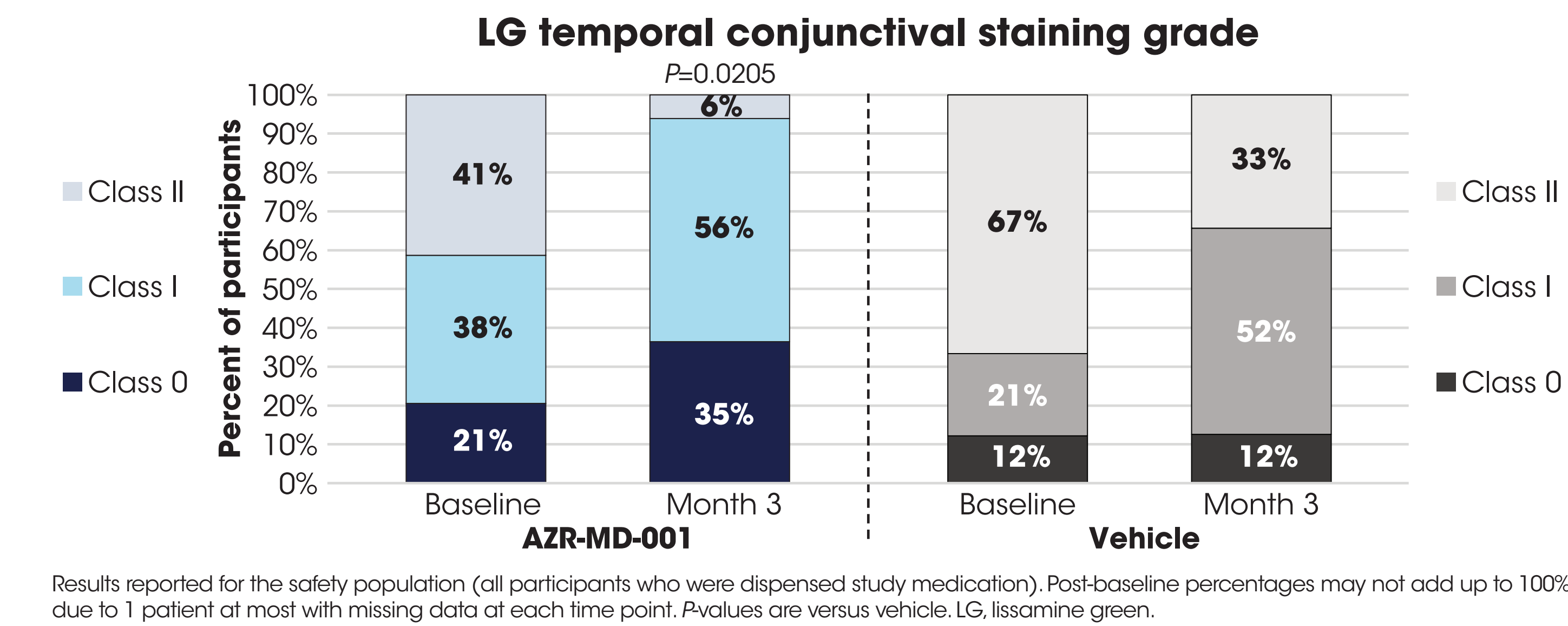
**FIGURE 1. FS CORNEAL STAINING: THERE WAS SIGNIFICANT DOWNWARD SHIFT IN CORNEAL STAINING WITH AZR-MD-001 VERSUS VEHICLE AS EARLY AS DAY 14 AND AT MONTH 3**



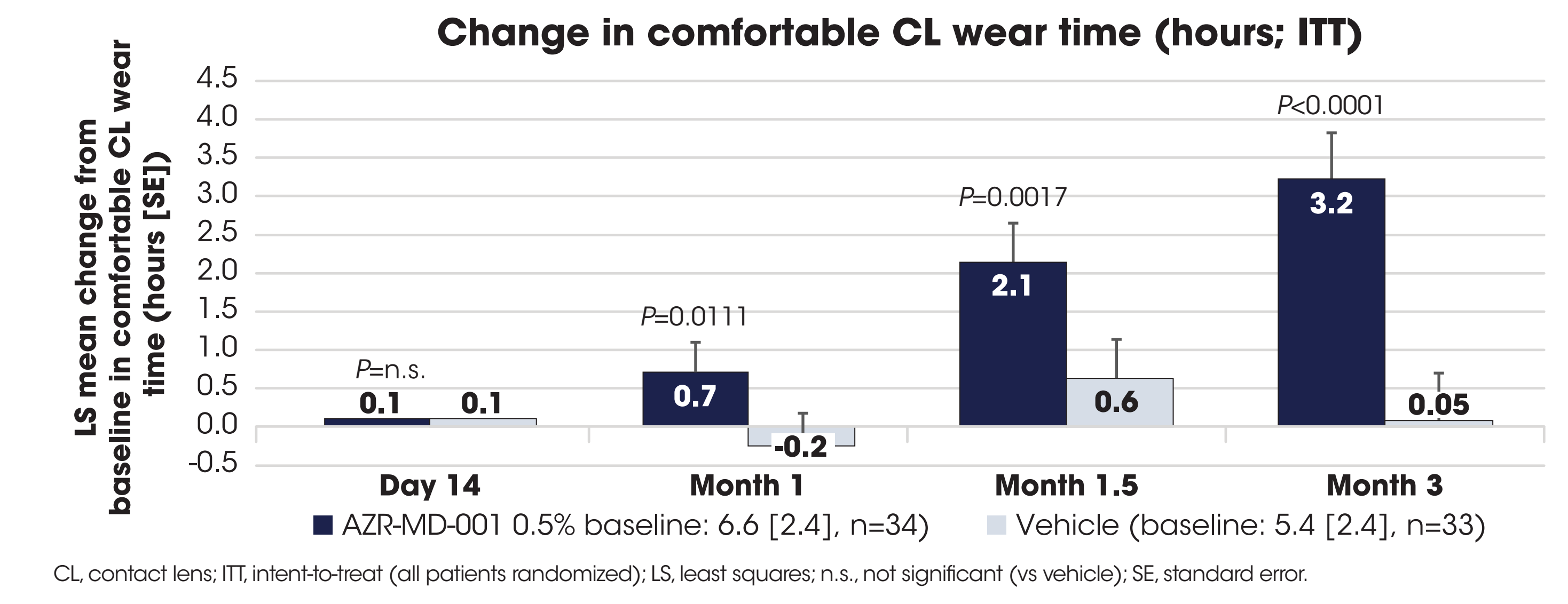
**FIGURE 2. LG CONJUNCTIVAL STAINING: SIGNIFICANTLY MORE PATIENTS TREATED WITH AZR-MD-001 THAN VEHICLE HAD REDUCED NASAL STAINING AT MONTH 3**



**FIGURE 3. LG CONJUNCTIVAL STAINING: SIGNIFICANTLY MORE PATIENTS TREATED WITH AZR-MD-001 THAN VEHICLE HAD REDUCED TEMPORAL STAINING AT MONTH 3**



**FIGURE 4. AZR-MD-001 SIGNIFICANTLY IMPROVED COMFORTABLE CL WEAR TIME VERSUS VEHICLE STARTING MONTH 1 THROUGH MONTH 3**



## SAFETY AND TOLERABILITY

- All TEAEs were mild to moderate, with no serious TEAEs, and no participants discontinuing study due to a TEAE.
- 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).
  - All events were self-limiting and were resolved within the first month of dosing.

**TABLE 2. OVERVIEW OF SAFETY**

Patients, n (%)	AZR-MD-001 0.5% (N=34)	VEHICLE (N=33)
Any related TEAE*	23 (67.6%)	0
Related TEAEs reported in ≥5% of patients in any arm		
Eye irritation	21 (61.8%)	0
Conjunctival hyperemia	2 (5.9%)	0
Any serious adverse event	0	0

Results reported for the safety population (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. There were 3 participants (9.1%) in the vehicle arm who experienced non-related TEAEs. TEAE, treatment-emergent adverse event.

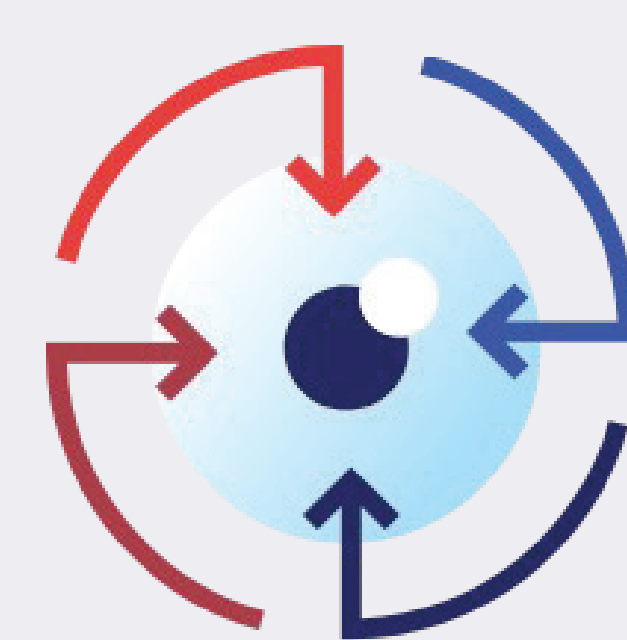
## CONCLUSIONS

- AZR-MD-001 0.5% treatment significantly improved corneal and conjunctival damage in patients with CLD and signs of MGD, with two- to four-fold increases in the percentage of patients with no staining.
- Treatment with AZR-MD-001 increased comfortable CL wear time by 3.2 hours compared to 0.05 hours with vehicle
- AZR-MD-001 was safe and well tolerated over 3 months of treatment.

## 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 (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 CL for ≥6 months, including wearing of the soft CL ≥3 weeks before the baseline visit, and wore or attempted to wear CL ≥4 times a week before the baseline visit; answered "No" to "Are you able to comfortably wear your lenses as long as you want?"; self-reported history of CL dryness/intolerance in the 6 months preceding baseline; and had a baseline Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score of >12
  - Excluded: Those with corneal staining ≥3 (between 33 and 100 dots) using the Oxford scheme
  - CL were to be used during the study and were removed for scheduled visits as well as 15 minutes before dosing.
- Treatment:** Patients randomized (1:1) to AZR-MD-001 0.5% or vehicle applied twice weekly to the lower eyelid just before bedtime
  - No conventional treatments allowed during the study
- 6 scheduled visits:** Screening, randomization/baseline, 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 Glands Yielding Liquid Secretion, (2) CLDEQ-8 total score, and (3) CLDEQ-8 fluctuating vision items
- Safety measures:** Treatment-emergent adverse events (TEAEs), fluorescein sodium (FS) corneal staining, and lissamine green (LG) conjunctival staining (LG only captured at baseline and Month 3)
- Analysis:** Counts and percentages are summarized; for staining endpoints the distribution of scores was compared between AZR-MD-001 and vehicle using Cochran-Mantel-Hanszel tests, controlling for baseline

### TEAEs



Classified using MedDRA version 25.1; summarized by incidence, nature, severity, and relatedness

### FS corneal staining



Assessed corneal damage by grading staining ~2 minutes after fluorescein application, using a slit lamp at 10x magnification and a yellow barrier filter and cobalt blue filter for illumination; grading based on the 6-point (0, I, II, III, IV, V) Oxford scheme<sup>5</sup>

### LG conjunctival staining



Assessed nasal and temporal conjunctival damage by grading staining with 3 minutes of applying LG strips to the superior bulbar conjunctiva of each eye; using low to moderate intensity white light; grading was based on the 6-point (0, I, II, III, IV, V) Oxford scheme<sup>5</sup>

### Comfortable CL wear time



Commonly used to assess the effects of changing CL, CL routines, or rewetting solutions; captured as the number of minutes with comfortable wear time

## Contact

Charles Bosworth  
Azura Ophthalmics Ltd, Tel Aviv, Israel  
charles.bosworth@azuraophthalmics.com

## References

1. Nichols KK, et al. *Invest Ophthalmol Vis Sci*. 2013;54(11):TF0514-9. 2. Dumbleton K, et al. *Invest Ophthalmol Vis Sci*. 2013;54(11):TF0520-36. 3. Stapleton F, et al. *Cont Lens Anterior Eye*. 2021;44(2):330-67. 4. Watson SL, et al. *Ocul Surf*. 2023;29:537-46. 5. *International Dry Eye Workshop (2007)*. *Ocul Surf*. 2007;5(2):108-52.

## Acknowledgements

The authors thank the patients who participated in this study. Medical writing support was provided by The Medicine Group, LLC (New Hope, PA, USA), which was funded by Azura Ophthalmics and in accordance with Good Publication Practice guidelines.

## Disclosures

**C. Bosworth:** Employment, stock options, and patent: Azura Ophthalmics. **M. Hinds:** Research grants: Alcon, Azura Ophthalmics, Core Research Group (Eli Lilly and Company), Kiara Pharmaceuticals, Novo Nordisk, Synergeyes, Ialys Therapeutics, and Vyluma; Consultant: Kiara Pharmaceuticals. **Honoraria:** Queensland University of Technology (School of Optometry and Vision Science); Travel support: Synergeyes. **E. Kassel:** Consultant and stock options: Azura Ophthalmics. **Y. Alster:** Owner, employment, stock options, and patent: Azura Ophthalmics.

