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Characteristics of Participants with Mild to Moderate MGD Utilizing AZR-MD-001 0.5% in a Randomized, Placebo-Controlled, Phase 3 Trial: The ASTRO Study

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BACKGROUND

- Meibomian gland dysfunction (MGD) is a chronic, progressive condition associated with blockage of meibomian glands and alteration of meibum quality[1]
- Abnormal keratin production and aggregation in patients with MGD alter meibum quality and quantity, leading to the blockage and atrophy of meibomian glands[2]
- The term MGD is regarded as appropriate for describing the functional abnormalities of the meibomian glands. Several ophthalmic, systemic, and medication-related factors may coexist with, or plausibly contribute to, the pathogenesis of MGD, including anterior blepharitis, contact lens wear, *Demodex folliculorum*, and dry eye disease (DED)[3]
- AZR-MD-001 (AZR) 0.5% is a keratolytic, keratostatic, and lipogenic ophthalmic ointment that has been shown in previous trials to be effective in improving signs and symptoms in patients with MGD[4-6]
- The objective was to review the population characteristics of participants that were enrolled in a Phase 3 study utilizing AZR 0.5% for the treatment of MGD and symptoms of DED compared to vehicle

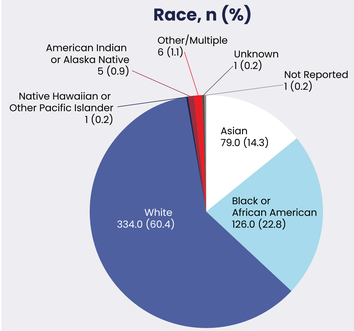
METHODS

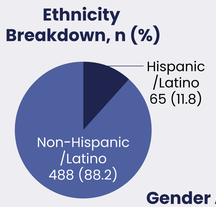
- **Trial Design:** Phase 3, multi-center, double-masked, placebo-controlled, randomized, parallel-group study (AZ202401; NCT06329791)
- Enrollment occurred between May 20, 2024 to Sept 8, 2024 (108 days)
- **Scales and Measures:**
  - Meibomian Gland Yielding Liquid Secretion Score (MGYLS)
    - Number of open glands
  - Meibomian Gland Score (MGS)
    - Meibum quality and expression of glands
  - Standard Patient Evaluation of Eye Dryness (SPEED)
    - Severity of dry eye disease symptoms (mild/moderate/severe)
  - Ocular Surface Disease Index (OSDI©)
    - Dry eye symptom presence and severity with subscales
  - Tear Breakup Time (TBUT)
    - Tear film evaporation rate
  - Ocular Discomfort Visual Analogue Scale (VAS)
    - Impact and incidence of ocular discomfort with subscales
- **Analyses:** number (n), mean (actual value, multiple imputation), standard error (SE) or standard deviation (SD), and percentage were calculated appropriately for participant demographics and disease characteristics using two populations:
  - The **Intent to Treat (ITT) population** included participants who were randomized to treatment at baseline
  - The **Safety Population** included participants who were randomized to treatment at baseline and applied at least one dose of medication
- **Inclusion Criteria:** Adult participants (≥18 years of age) with MGD (MGS score of ≤12 in both eyes at baseline and screening), evidence of mild to moderate evaporative DED (reported dry eye symptoms within the past 3 months, SPEED score of ≥6, OSDI total score ≥13 and <34, TBUT <10 in both eyes), Schirmers >5 mm in either eye, absence of significant signs of inflammation (corneal staining <3) and normal intraocular pressure

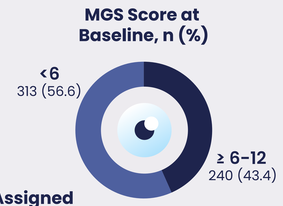
RESULTS

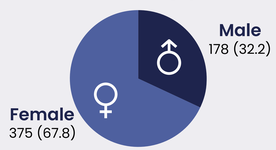
PARTICIPANT DEMOGRAPHICS AT BASELINE (SAFETY POPULATION)

Pooled Groups (N=553)









Age (Years)

Min	Mean (SD)	Max
19	57.4 (14.3)	93

Duration of Evaporative DED at Baseline, n (%)

<5 years	≥5 years
178 (32.2)	375 (67.8)

DED, Dry Eye Disease; max, maximum; min, minimum; MGS, Meibomian Gland Score; n, number; SD, standard deviation.

PARTICIPANT DISEASE CHARACTERISTICS AT BASELINE (ITT POPULATION)

		POOLED GROUPS (n=562)
MGYLS Score	Mean (SE) Range (min, max)	2.2 (0.06) 0, 6.0
Schirmer's	Mean (SE) Range (min, max)	15.0 (0.41) 6.0, 35.0
SPEED Score	Mean (SE) Range (min, max)	13.1 (0.19) 6.0, 28.0
Total OSDI© Score	Mean (SE) Range (min, max)	25.1 (0.22) 13.9, 33.3
TBUT (seconds)	Mean (SE) Range (min, max)	3.5 (0.05) 1.05, 7.62
Total VAS Score	Mean (SE) Range (min, max)	37.4 (0.94) 0, 93.0

Max, maximum; MGS, Meibomian Gland Secretion; MGYLS, Meibomian Gland Yielding Liquid Score; min, minimum; OSDI, Ocular Surface Disease Index; SE, standard error; SPEED, Standard Patient Evaluation of Eye Dryness; TBUT, Tear Breakup Time; VAS, Visual Analog Scale.

SUMMARY

- Participants enrolled in the study included adults with a wide range of ages, mild to moderate MGD, a mean score indicating moderate DED, along with a clear DED symptom burden
- The speed of enrollment of this Phase 3 study demonstrated that it is plausible to successfully enroll participants with mild to moderate MGD and DED based upon glandular morphology and dry eye symptoms to advance therapeutic outcomes in an efficient manner

Contact

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References

1. Knop E, et al. *Invest Ophthalmol Vis Sci.* 2011;52:1938-78; **2.** Nichols JJ, et al. *Invest Ophthalmol Vis Sci.* 2013;54:TFOS1-6; **3.** Nichols KK, et al. *Invest Ophthalmol Vis Sci.* 2011;52:1922-9; **4.** Watson SL, et al. *Ocul Surf.* 2023;29:537-46; **5.** Downie LE, et al. *Ocul Surf.* 2025;35:15-24; **6.** Stapleton F, et al. *Ocul Surf.* 2025; 31:36:190-197.

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Disclosures

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C: Consultant, E: Employment, P: Patent; R: Research funding/support; S: Stock;