1752 - 0514

Lid Telangiectasia Following Treatment With AZR-MD-001 0.5% vs. Vehicle in Contact Lens Wearers With Meibomian Gland Dysfunction and Dry Eye: The ARIES Phase 2b Study

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BACKGROUND

- Signs of Meibomian Gland Dysfunction (MGD) and symptoms of dry eye disease (DED) may result in discomfort while wearing contact lenses (CLs), or lead to discontinuation of CL use[1]
- Contact lens-related discomfort can occur in a significant number of patients with pre-existing MGD and DED, with symptoms becoming exacerbated when CLs are worn[2]
- Lid telangiectasias are a common clinical sign in patients with MGD[3], and the severity of lid telangiectasias are linked to both the severity of MGD and the ocular surface inflammatory response[4,5]
- AZR-MD-001 (AZR) 0.5% is an investigational keratolytic ophthalmic ointment containing selenium sulfide that is applied twice weekly at bedtime directly onto the lower lid margin
- Previous clinical trials utilizing AZR in participants with DED and MGD (NCT05548491, NCT03652051, and NCT03972501) have demonstrated significant increases in the number of open glands yielding meibum[6-8], improvements to quality of meibum secretion[6-8], and improvement in comfortable CL wear time[8]
- Analyses were undertaken to identify if treatment with AZR resulted in changes in severity and presence of lid telangiectasias over time compared to vehicle

METHODS

- This phase 2b, multi-center, vehicle-controlled, double-blind study (ARIES, NCT03972501) was conducted in participants with MGD and DED who also wore CLs (n=67) to assess the effect of AZR on the signs and symptoms of DED over 3 months
- The main entry criteria included participants (18 years or older) with DED symptoms (CLDEQ-8 score >12), MGD defined as Meibomian Gland Score (MGS) <12, and the inability to comfortably wear their CLs as long as desired
- Participants were enrolled into the study and randomized (1:1) to AZR (n=34) or vehicle (n=33) applied to the lower eyelid before bedtime twice weekly for 3 months
- Lid margin telangiectasias were identified using slit-lamp biomicroscopy by a masked examiner and graded as none, trace, mild, moderate, or severe at each visit (Baseline, Day 14, Month 1.5 and Month 3; see ARVO poster #1754 – 0516 for a study methods diagram)
- Analyses calculated the mean percentage change from baseline to Month 3 using shift tables
  - Analyses were completed to identify the differences in distribution of severity within groups at Month 1.5 and Month 3 using Cochran-Mantel-Haenszel tests controlling for baseline value
  - Analyses to compare groups in improvements in severity by at least one grade from baseline were completed with a Fisher's exact test at Month 3

RESULTS

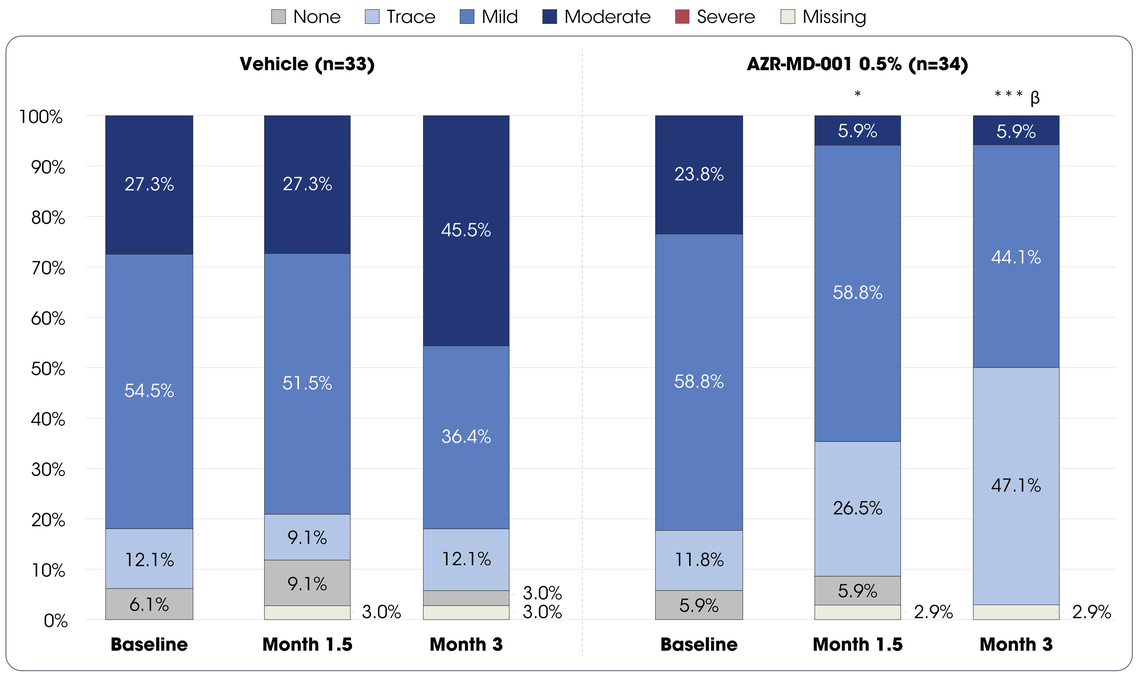
TABLE 1. BASELINE CHARACTERISTICS AND DEMOGRAPHICS[8]

	AZR-MD-001 0.5% (n=34)	Vehicle (n=33)
Baseline Demographics		
Age (years)		
Mean (SD)	46.7 (12.8)	49.4 (14.3)
Median (range)	47.5 (18-76)	51.0 (18-72)
Sex, n (%)		
Female	29 (85)	26 (79)
Male	5 (15)	7 (21)
Race, n (%)		
White	26 (76)	26 (79)
Asian	8 (24)	7 (21)
Baseline Characteristics		
Number of MGYLS, mean (SD)*	2.8 (0.8)	3.0 (0.6)
CLDEQ-8 Score, mean (SD)*	21.5 (0.93)	22.2 (0.96)
OSDI Total Score, mean (SD)	30.7 (2.93)	35.4 (3.51)
MGS Score, mean (SD)*	8.4 (1.7)	8.7 (1.6)
TBUT (seconds), mean (SD)	6.3 (2.2)	5.5 (1.6)
CWT (hours), mean (SD)*	6.6 (2.4)	5.4 (2.4)
Participants able to wear their CLs as long as desired; n (%)*	0 (0%)	0 (0%)

Adapted from Stapleton, et al. *Ocul Surf* 2025. *Associated with study inclusion/exclusion criteria.
CLDEQ-8, Contact Lens Dry Eye Questionnaire-8; CWT, comfortable wear time; MGS, Meibomian Gland Secretion; MGYLS, Meibomian Glands Yielding Liquid Secretion; OSDI, Ocular Surface Disease Index; SD, standard deviation; TBUT, fluorescein tear break-up time.

- Participants treated with vehicle showed a shift towards higher frequency and severity in telangiectasias over time from Baseline to Month 3, whereas participants treated with AZR demonstrated a shift towards a decrease in severity (**Figure 1**)
  - The differences in distribution of severity of participants treated with AZR vs. vehicle were statistically significantly different at both Month 1.5 ($P = 0.0346$) and Month 3 ($P = 0.0003$)
- The differences between groups achieving at least one grade improvement at Month 3 were statistically significantly higher for those treated with AZR than vehicle at Month 3 ($P = 0.0027$)

FIGURE 1. PRESENCE AND SEVERITY OF LID TELANGIECTASIA BY TREATMENT GROUP



Difference from baseline at Month 1.5 and 3: *P<0.05, **P<0.01, ***P<0.001. Difference between treatment groups (AZR vs. vehicle) at Month 3: $^{\beta}P$<0.05, $^{\beta}P$<0.01.

SUMMARY

- In participants who presented with signs of MGD and symptoms of DED, twice-weekly treatment with AZR resulted in significantly improved lid telangiectasia severity, compared to treatment with vehicle which showed an increase in severity over time
- These data demonstrate that AZR impacts mechanisms of MGD and DED beyond just the quality and release of meibum from the meibomian glands
- Improvements in telangiectasias after treatment with AZR indicate that the treatment may mitigate downstream inflammatory effects on the lid margin

AZR-MD-001 is an investigational product that has not been approved by the FDA.

Contact

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