

3-Month Safety Data Outcomes From a Phase 3 Study of AZR-MD-001 0.5% (ASTRO) for the Treatment of Dry Eye Disease and Signs of Meibomian Gland Dysfunction

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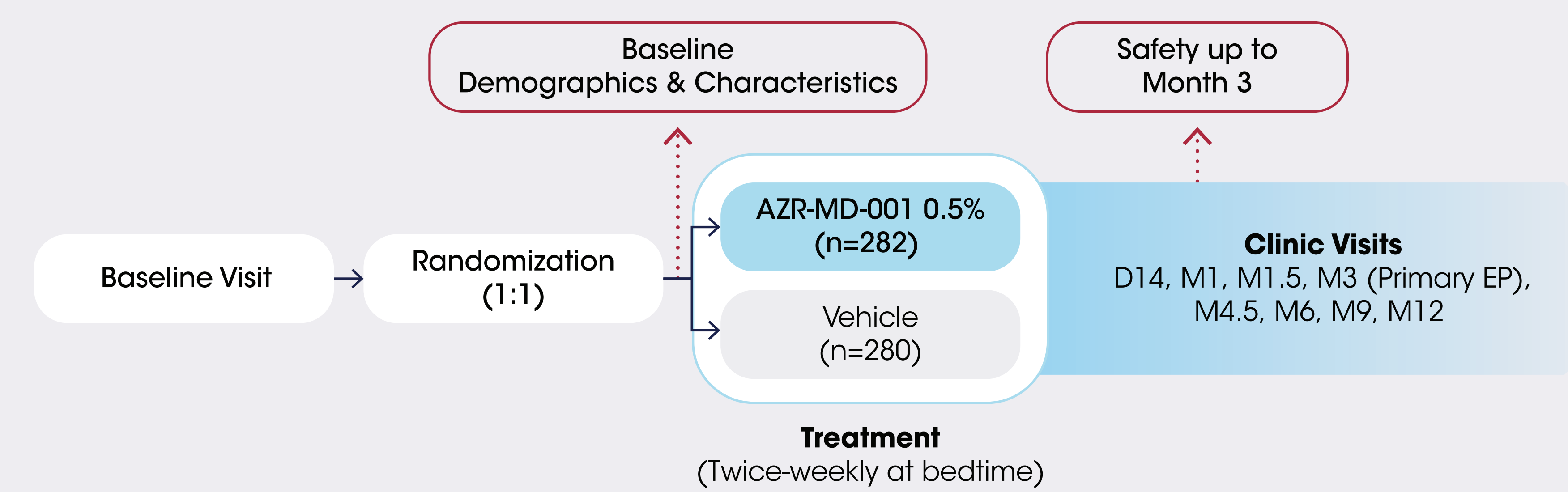
BACKGROUND

- AZR-MD-001 (AZR) 0.5% is a keratolytic ophthalmic ointment containing selenium sulfide that is applied twice weekly at bedtime directly onto the meibomian gland orifices of the lower lid margin
- Previous studies in participants with mild to moderate evaporative dry eye disease (DED) with signs of meibomian gland dysfunction (MGD) who were treated with AZR have demonstrated safety and efficacy with up to 6 months of dosing (NCT03972501, NCT03652051)^{1,2,3}
- ASTRO is a randomized, vehicle-controlled, phase 3 safety study (NCT06329791) in participants with a broader spectrum of DED-related MGD
- The study was designed to evaluate safety in a larger and more expansive patient population during months of dosing

METHODS

- In this multi-center study (15 trial sites, AZ202401, NCT06329791), 562 participants with DED and signs of MGD were randomized (1:1) to AZR 0.5% (n=282) or vehicle (n=280) applied to the lower eyelid meibomian glands twice weekly at bedtime
- Participants were seen in the clinic at Baseline, Day 14, Months 1, 1.5, 3, 4.5, 6, 9, and 12 (Figure 1)
- Outcomes included incidence, relatedness, and severity of treatment-emergent adverse events (TEAEs), and discontinuation incidence and reasons
- Safety data was collected spontaneously and at clinic visits
- Baseline characteristics are reported for the intent to treat (ITT) population (all participants randomized to a study group)
- Safety outcomes are reported for the Safety population (all participants randomized to a treatment group that applied at least one treatment) and were measured from Baseline to Month 3 for these analyses

FIGURE 1. PARTICIPANT FLOW DIAGRAM



RESULTS

- Most participants were female (67.8%, 375/553) with a longer history of DED (>5 years 67.8%, 375/553)
- Participants in the trial exhibited characteristics of both evaporative DED and mixed (evaporative and inflammatory) DED (Table 1)
- The most common TEAEs related to treatment were superficial punctate keratitis (AZR: 1.4%, vehicle: 0.7%), application site pain (AZR: 1.4%, vehicle: 0%), and instillation site irritation (AZR: 1.1%, vehicle: 0%) (Table 2)
- All ophthalmic TEAEs were mild or moderate; no severe ophthalmic TEAEs were reported (Table 3) and there were no serious TEAEs related to treatment (Table 4)
- Each group had one participant (AZR=0.4%, vehicle=0.4%) discontinue due to AEs but these discontinuations were not deemed related to treatment (Table 4)

RESULTS (CONT.)

TABLE 1. BASELINE DEMOGRAPHICS AND CHARACTERISTICS (ITT POPULATION)

	AZR-MD-001 0.5% (n=282)	Vehicle (n=280)
Age (years)		
Mean (SD)	57.2 (14.5)	57.6 (14.2)
Range (min, max)	20, 88	19, 93
Gender, n (%)		
Male	93 (33.6)	85 (30.8)
Female	184 (66.4)	191 (69.2)
Race, n (%)		
American Indian/Alaskan Native	2 (0.7)	3 (1.1)
Asian	35 (12.6)	44 (15.9)
Black/African American	68 (24.5)	58 (21.0)
Native Hawaiian/Pacific Islander	1 (0.4)	0 (0)
White	166 (59.9)	168 (60.9)
Other/Multiple	3 (1.1)	3 (1.1)
Unknown	1 (0.4)	0 (0)
Not Reported	1 (0.4)	0 (0)
Duration of Evaporative DED, n (%)		
<5 years	89 (32.1)	89 (32.2)
≥5 years	188 (67.9)	187 (67.8)
MGS Score at Baseline, n (%)		
<6	121 (43.7)	119 (43.1)
≥6	156 (56.3)	157 (56.9)
Schirmer's (mm)*		
Mean (SD)	14.7 (9.7)	15.3 (10.0)
Range (min, max)	6, 35	6, 35

*Safety population, AZR n=277, vehicle n=276.
DED, dry eye disease; ITT, intent to treat; MGS, Meibomian Gland Secretion; SD, standard deviation.

TABLE 2. ADVERSE EVENTS (SAFETY POPULATION)

n (%)	AZR-MD-001 0.5% (n=277)	Vehicle (n=276)
Incidence of Ophthalmic TEAEs (in either eye)	29 (10.5)	9 (3.3)
Severity of Ophthalmic TEAEs		
Mild	24 (8.7)	7 (2.5)
Moderate	8 (2.9)	2 (0.7)
Severe	0 (0)	0 (0)
TEAEs Reported in ≥0.5% of Participants Considered Related to Treatment		
Superficial Punctate Keratitis	4 (1.4)	2 (0.7)
Application Site Pain	4 (1.4)	0 (0)
Instillation Site Irritation	3 (1.1)	0 (0)

TEAEs, treatment-emergent adverse events.

TABLE 3. SEVERITY OF ADVERSE EVENTS (SAFETY POPULATION)

TEAEs (any relation to treatment); n (%)	AZR-MD-001 0.5% (n=277)			Vehicle (n=276)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Superficial Punctate Keratitis	2 (0.7)	2 (0.7)	0 (0)	2 (0.7)	0 (0)	0 (0)
Application Site Pain	5 (1.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Instillation Site Irritation	2 (0.7)	0 (0)	0 (0)	1 (0.4)	0 (0)	0 (0)

Application and instillation sites were defined as the lid margin where the treatment was applied.
TEAEs, treatment-emergent adverse events.

TABLE 4. STUDY DISCONTINUATIONS AND SERIOUS TEAEs (ITT POPULATION)

n (%)	AZR-MD-001 0.5% (n=282)	Vehicle (n=280)
Primary Reason for Study Discontinuation	8 (2.8)	10 (3.6)
Adverse Event ^a	1 (0.4)	1 (0.4)
Lost to Follow-Up	2 (0.7)	4 (1.4)
Physician Decision	0 (0)	1 (0.4)
Withdrawal by Subject	4 (1.4)	4 (1.4)
Other	1 (0.4)	0 (0)
Serious TEAEs Related to Treatment*	0 (0)	0 (0)
Serious TEAEs*	6 (2.2)	5 (1.8)

^aThere were no AEs considered related to treatment that led to study discontinuation. *Safety population, AZR n=277, vehicle n=276.
TEAEs, treatment-emergent adverse events.

SUMMARY

- The use of AZR 0.5% over 3 months in an expanded patient population with evaporative and mixed DED and signs of MGD was found to be safe and well-tolerated with no drug-related discontinuations, low rates of mild to moderate ophthalmic AEs, and no severe ophthalmic AEs reported.

Contact

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Disclosures

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C: Consultant or Honoraria, **E:** Employment, **P:** Patent, **R:** Research funding/support, **S:** Stock.

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

