5676 - B0071

Dosing Methods, Instructions for Use, and Safety Data Outcomes from a Phase 3 Study Evaluating the Efficacy and Safety of AZR-MD-001 0.5% for the Treatment of MGD and DED: The ASTRO Study

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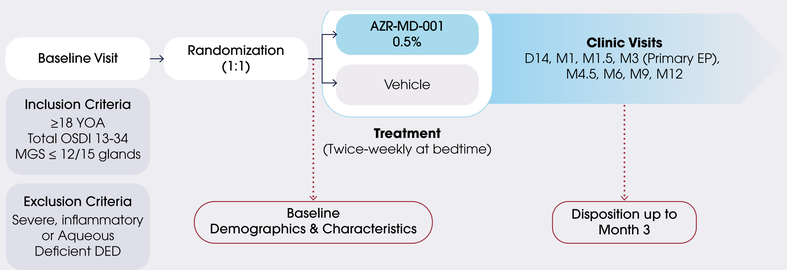
BACKGROUND

- Meibomian gland dysfunction (MGD) is associated with alteration of meibum quality[1] leading to 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 ophthalmic ointment containing selenium sulfide that is applied directly onto the lower lid margin and the meibomian gland orifices twice weekly, prior to sleep
- Unlike standard ophthalmic ointments where the dosed amount is poorly controlled and is typically applied onto the ocular surface and lower fornix, the dosing methods and instructions for use for AZR 0.5% have been developed to both standardize the amount and the location of drug application, and to improve the safety and tolerability of the drug
- The objective was to analyze the incidence of safety events across the entire population in a large trial using AZR 0.5% or vehicle in participants with MGD and mild to moderate DED

METHODS

- **Trial Design**: Phase 3, multi-center, double-masked placebo-controlled, randomized parallel group study (AZ202401; NCT06329791)
- Participants with MGD and DED were randomized (1:1) to AZR 0.5% or vehicle applied twice weekly prior to sleep for 3 months
  - For scales and measures, see poster 5675 - B0070
  - For detailed study flow, see Figure 1
- Participants utilized a Dispensing Aid into which the medication tube was inserted to ensure accurate dose volume, and were instructed on proper application of the drug to the lid margin through an instruction video and printed quick guide
- A practice application was completed by each participant and observed by the investigator prior to the first at-home dose
- Incidence/severity of treatment-emergent adverse events (TEAEs) and discontinuation frequency/reasons were collected for all participants who were randomized to treatment in the safety population (all participants randomized to a treatment group that received at least one treatment)

FIGURE 1. STUDY FLOW DIAGRAM



D, day; DED, Dry Eye Disease; M, month; MGS, Meibomian Gland Score; OSDI, Ocular Surface Disease Index; ITT, intent to treat; YOA, years of age.

- **Analyses:** Pooled data from a Phase 3 study of AZR 0.5% and vehicle for the treatment of mild to moderate MGD and DED were analyzed by percentage for the incidence, severity, relatedness to treatment, and discontinuations to demonstrate the safety across treatment groups

RESULTS

TABLE 1. PARTICIPANT DEMOGRAPHICS AND CHARACTERISTICS AT BASELINE (SAFETY POPULATION)

	POOLED GROUPS (N=553)
Age (years)	
Mean (SD)	57.4 (14.3)
Range (min, max)	19, 93
Gender Assigned at Birth, n (%)	
Male	178 (32.2)
Female	375 (67.8)
Race, n (%)	
Asian	79 (14.3)
Black or African American	126 (22.8)
White	334 (60.4)
Native Hawaiian or Other Pacific Islander	1 (0.2)
American Indian or Alaska Native	5 (0.9)
Other/Multiple	6 (1.1)
Unknown	1 (0.2)
Not Reported	1 (0.2)
Ethnicity, n (%)	
Hispanic/Latino	65 (11.8)
Non-Hispanic/Latino	488 (88.2)
MGS Score, n (%)	
<6	240 (43.4)
≥6-12	313 (56.6)
Duration of Evaporative DED, n (%)	
<5 years	178 (32.2)
≥5 years	375 (67.8)

DED, dry eye disease; max, maximum; min, minimum; MGS, meibomian gland score; n, number; SD, standard deviation.

TABLE 2. SAFETY OUTCOMES (SAFETY POPULATION)

	POOLED GROUPS (n=553)
Incidence of Ophthalmic TEAEs (in either eye); n (%)	26 (4.7)
Severity of Ophthalmic TEAEs; n (%)	
Mild	16 (2.9)
Moderate	4 (0.7)
Severe	0 (0)
TEAEs reported in ≥ 0.5% of Participants Considered Related to Treatment; n (%)	6 (1.1)
Superficial Punctate Keratitis	4 (0.7)
Application Site Pain	3 (0.5)
Instillation Site Irritation	
Primary Reason for Study Discontinuation; n (%)	
Adverse Event*	2 (0.4)
Lost to Follow-Up	6 (1.1)
Physician Decision	1 (0.2)
Withdrawal by Subject	8 (1.4)
Other	1 (0.2)
Serious TEAEs Considered Related to Study Drug; n (%)	0 (0%)

*There were no adverse events considered related to treatment that led to study discontinuation.
N, number; TEAE, treatment-emergent adverse event.

RESULTS (CONT.)

TABLE 3. TEAE SEVERITY (SAFETY POPULATION)

	POOLED GROUPS (n=553)		
	MILD	MODERATE	SEVERE
Superficial Punctate Keratitis; n (%)	4 (0.7)	2 (0.4)	0 (0)
Application Site Pain; n (%)	4 (0.7)	0 (0)	0 (0)
Instillation Site Irritation; n (%)	3 (0.5)	0 (0)	0 (0)

N, number.

SUMMARY

- The use of AZR 0.5% or vehicle over 3 months was found to be safe and well-tolerated with no treatment-related discontinuations, low rates of ophthalmic TEAEs, with TEAEs being mild to moderate in severity, and no severe ophthalmic TEAEs reported as related to treatment
- The training, dosing method, and application instructions were important factors in participant application of the treatment, and likely contributed to the low incidence of TEAEs

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.

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