Lotilaner Ophthalmic Solution, 0.25% for the Treatment of *Demodex* blepharitis Patients with Meibomian Gland Dysfunction

Presenting Author: Mitchell Shultz, MD[1]

Coauthors: Preeya K. Gupta, MD[2]; Patrick Vollmer, OD, FAAO[3]; Leslie O'Dell, OD[4]; Kavita Dhamdhere, MD, PhD[4]; Elizabeth Yeu, MD[4]

[1]Shultz Chang Vision, Los Angeles, CA; [2]Triangle Eye Consultants, Raleigh, NC; [3]Vita Eye Clinic, Shelby, NC; [4]Tarsus Pharmaceuticals, Irvine, CA

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Disclosures

- Mitchell Shultz: C, R, S for Tarsus Pharmaceuticals, Inc.
- Preeya K. Gupta: C, R, S for Tarsus Pharmaceuticals, Inc.
- Patrick Vollmer: C, R, S for Tarsus Pharmaceuticals, Inc.
- Leslie O'Dell: EO, R, SU of Tarsus Pharmaceuticals, Inc.
- Kavita Dhamdhere: EO, SU of Tarsus Pharmaceuticals, Inc.
- Elizabeth Yeu: EO, SU of Tarsus Pharmaceuticals, Inc.

Consultant (C); Employee (EO); Researcher (R); Shareholder (SU); Speaker (S)

Background and Purpose

- **57%** of patients with meibomian gland disease have *Demodex* blepharitis (DB)[1]
- ***Demodex* infestation** impacts the function and structure of meibomian glands,[2,3] and can **trigger meibomian gland disease via two key mechanisms**:

Inflammation process

- *Demodex* mites induce inflammatory byproducts and mediators, eliciting **inflammation**[3-6]

Obstruction of the gland orifices

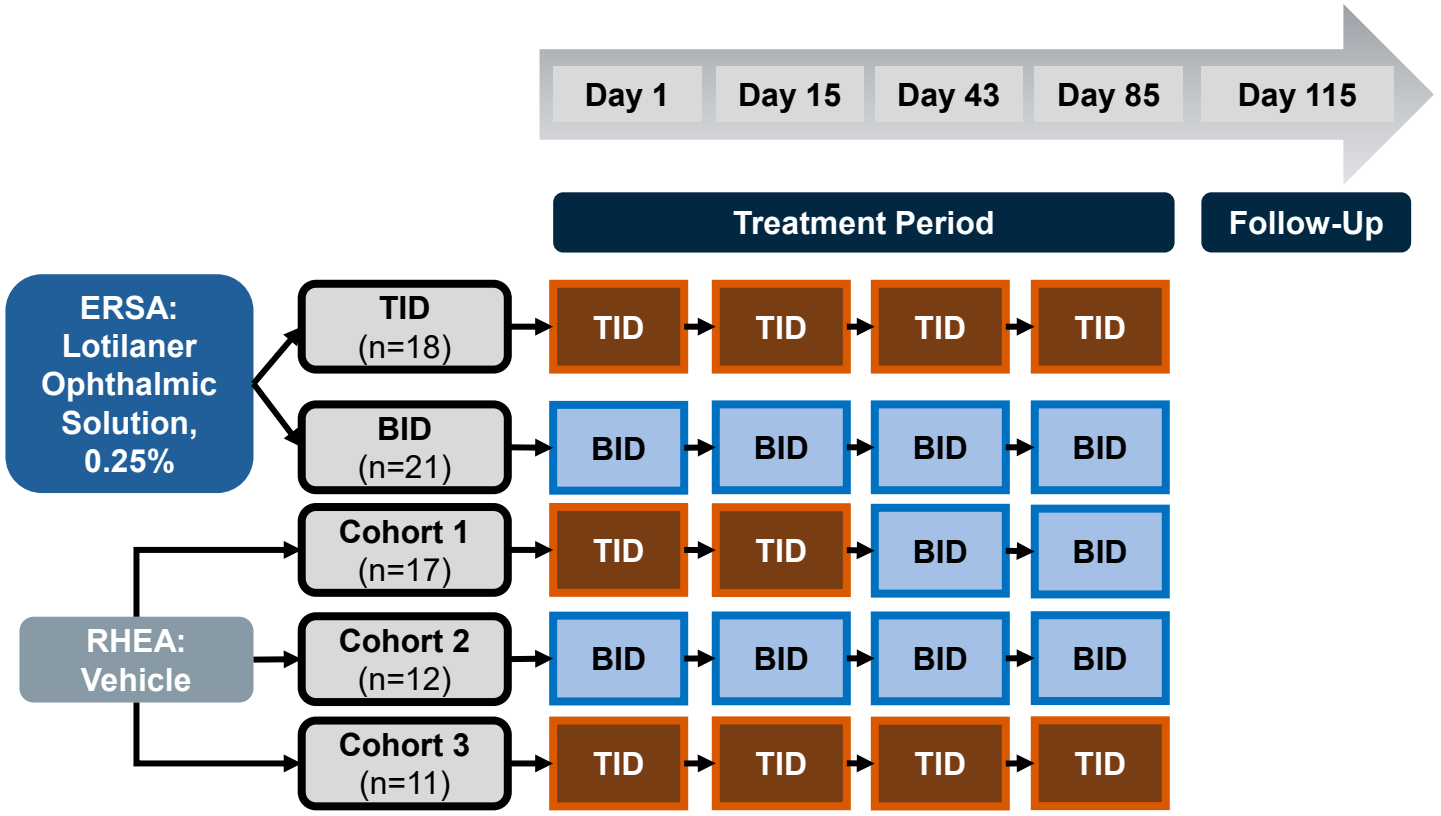
- Inflammation leads to **edema of the eyelid margin** and **reduces the diameter of the gland orifice** and outflow potential[3-5]
- Obstruction of the gland orifices **negatively affects meibum quality**, leading to thickened meibum and meibomian gland acini destruction and atrophy[2-5]

***Purpose:* The ERSA/RHEA study aimed to investigate the safety and efficacy of lotilaner ophthalmic solution 0.25%, compared to vehicle, in meibomian gland disease outcomes among DB patients with meibomian gland disease.**

1. Trattler W et al. *Clin Ophthalmol*. 2022;16:1153-1164; 2. Lee WJ et al. *Sci Rep*. 2023;13(1):16324; 3. Cheng S et al. *Medicine (Baltimore)*. 2019;98(19):e15595; 4. Rhee MK et al. *Eye Contact Lens*. 2023;49(8):311-318; 5. Liu J et al. *Curr Opin Allergy Clin Immunol*. 2010;10(5):505-510; 6. Geerling G et al. *Ocul Surf*. 2017;15(2):179-192.

Study Design

- Meibomian gland function was evaluated by assessing 15 central glands of the lower eyelid and scoring meibum quality on a scale of 0 (no secretion) to 3 (clear liquid secretion)



ERSA/RHEA Pooled analysis*

Key outcomes:

- Safety and tolerability
- DB outcomes: Collarette reduction
- Meibomian gland function:
  - Meibomian gland secretion score (MGSS)
  - Meibomian glands yielding any liquid (score 2-3) (MGYLS)
  - Meibomian glands yielding clear liquid (score 3) (MGYCLS)
- Patient-reported outcomes (Visual analog scale [VAS])

*After establishing baseline equivalencies between the study groups, ERSA and RHEA were pooled for analysis.

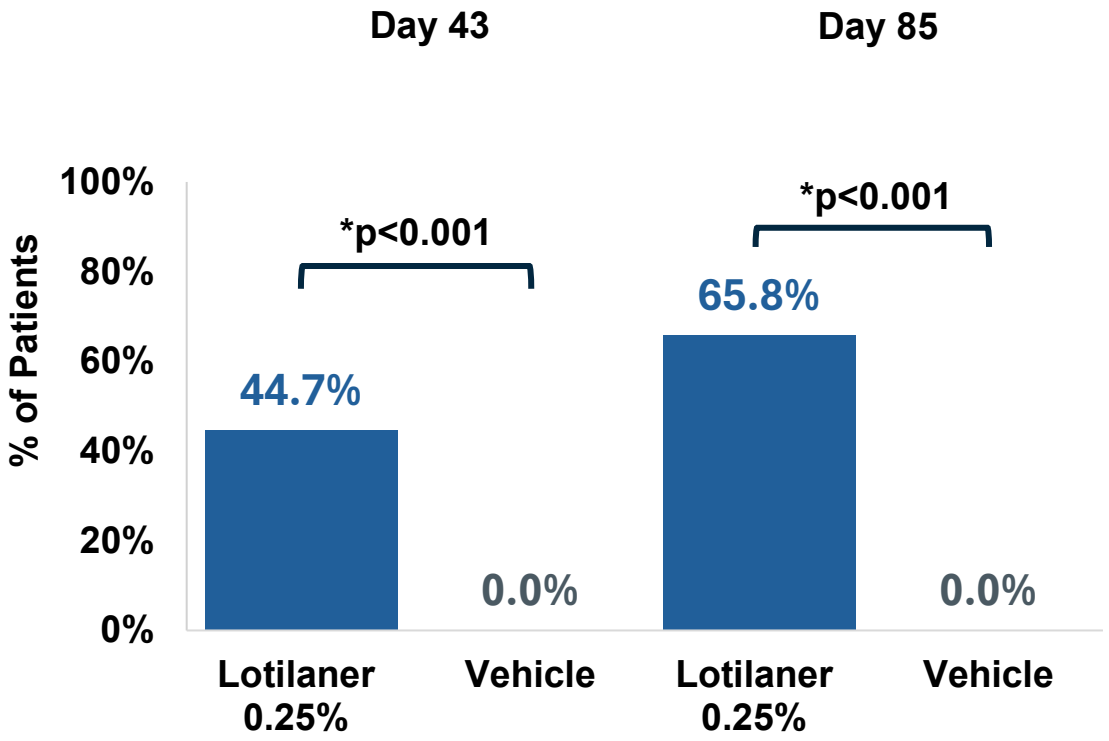
Demographics and Baseline Characteristics

- Demographics and baseline characteristics were similar between lotilaner 0.25%-treated and vehicle-treated patients:

Characteristic	ERSA: Lotilaner ophthalmic solution 0.25% (N=39)	RHEA: Vehicle (N=40)	p-value
Age in years, Mean (SD)	63.7 (14.7)	63.4 (12.1)	>0.9
Sex, n (%) Female Male	 23 (59.0) 16 (41.0)	 23 (57.5) 17 (42.5)	>0.9
Race, n (%) White African American/Black Asian	 33 (84.6) 3 (7.7) 3 (7.7)	 34 (85.0) 3 (7.5) 3 (7.5)	>0.9
Collarette Grade, Mean (SD)	2.9 (0.8)	2.7 (0.8)	0.2
Meibomian Gland Secretion Score, Mean (SD)	22.0 (5.1)	22.0 (4.8)	>0.9
Number of Expressible Glands, Mean (SD)	7.1 (4.0)	7.4 (3.3)	0.8
Number of Glands Yielding Clear Liquid Secretion (Score 3), Mean (SD)	0.8 (1.1)	0.7 (1.1)	0.7

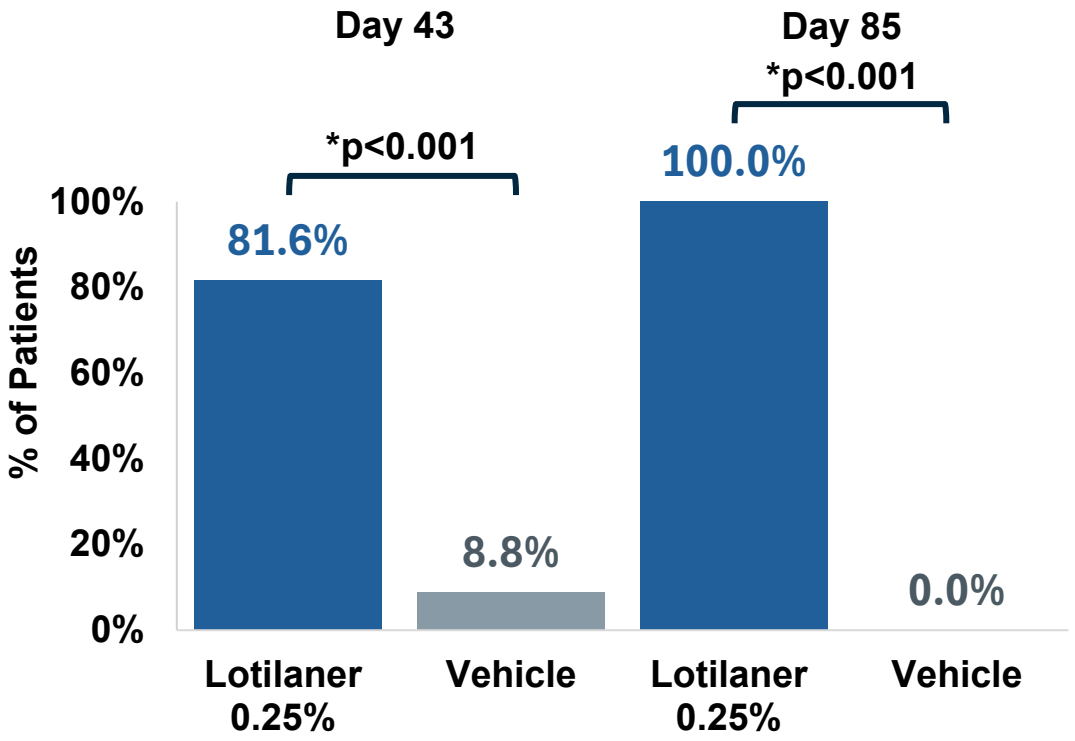
Greater percentage of lotilaner 0.25%-treated patients demonstrated collarette reduction compared to vehicle

Collarette Reduction to 0-2 Collarettes (Grade 0)



N	38	34	38	33

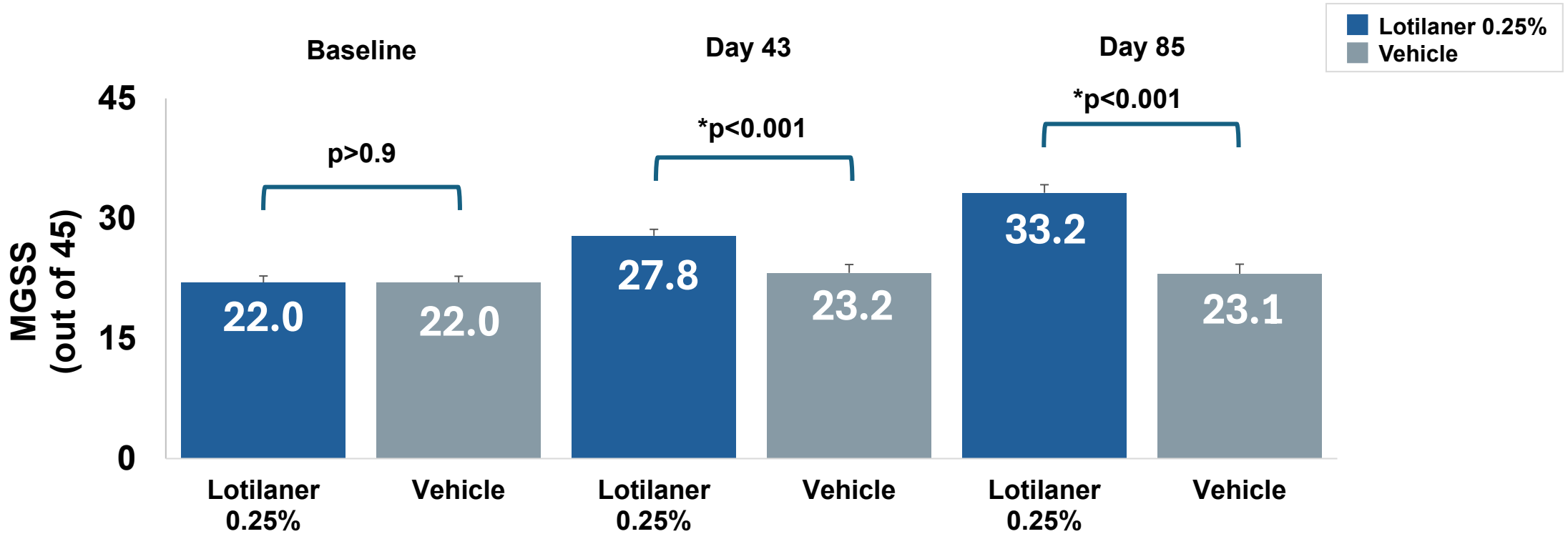
Collarette Reduction to 0-10 Collarettes (Grade 0-1)



N	38	34	38	33

*Statistically significant

Lotilaner 0.25% demonstrated significant improvements in Meibomian Glands Secretion Score (MGSS) at 6 and 12 weeks

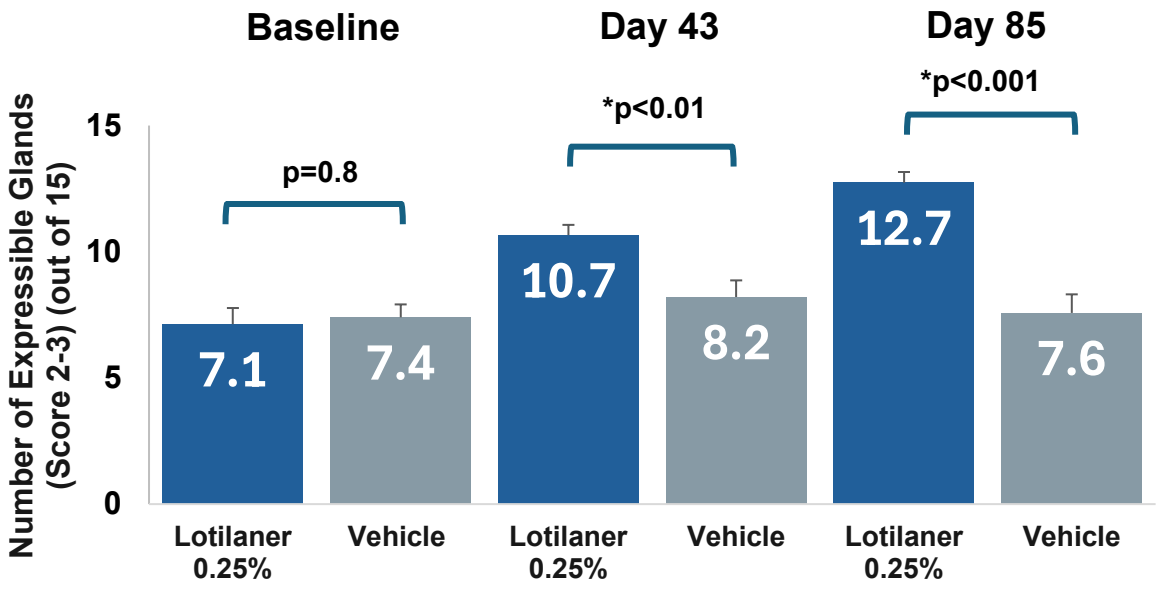


N	39	40	38	34	38	33
p-value†			<0.001	0.074	<0.001	0.095
Mean Δ			+5.7	+1.8	+11	+1.6

*Statistically significant †Paired t-test from baseline

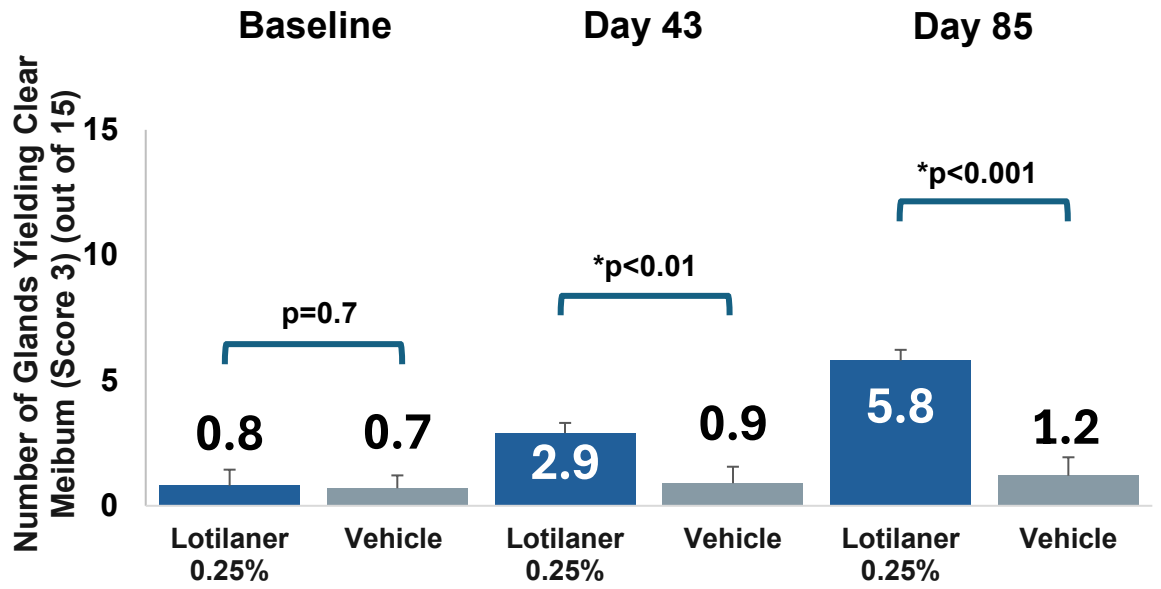
Lotilaner 0.25% demonstrated significant improvements in Meibomian Glands yielding Any or Clear Liquid at 6 and 12 weeks

MGYLS (Score 2 or 3)



N	39	40	38	34	38	33
p-value†			<0.001	0.048	<0.001	0.3
Mean Δ			+3.3	+1.4	+5.4	+0.7

MGYCLS (Score 3)

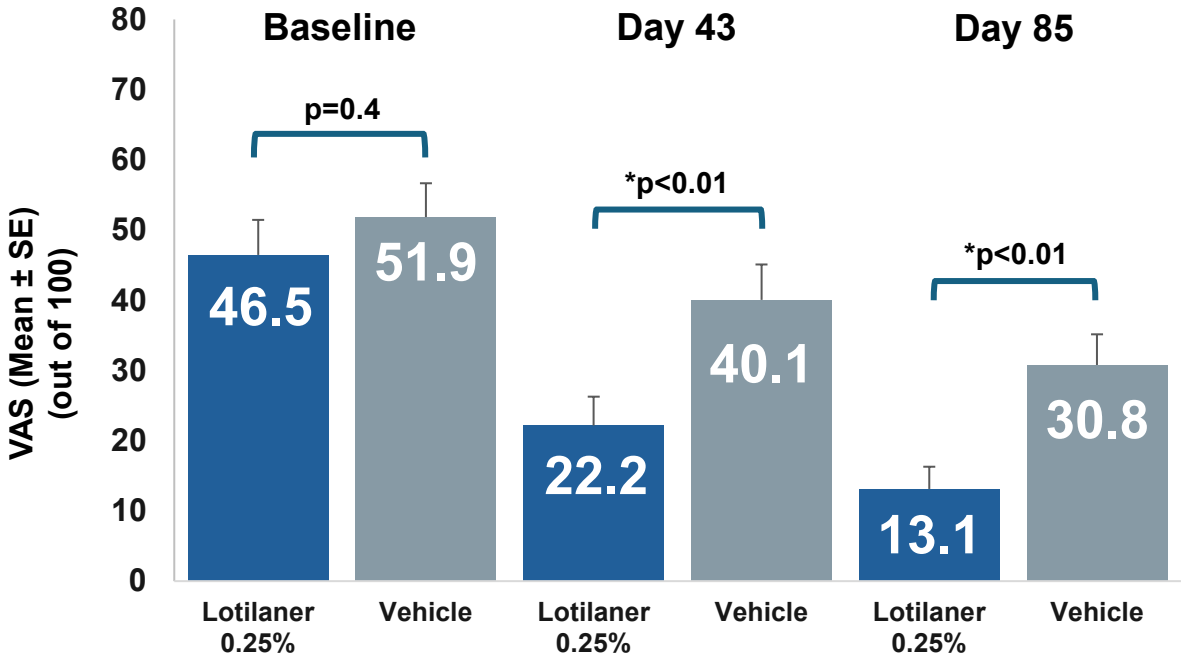


N	39	40	38	34	38	33
p-value†			<0.001	0.078	<0.001	0.013
Mean Δ			+2.1	+0.3	+5.1	+0.7

*Statistically significant †Paired t-test from baseline
MGYLS = meibomian glands yielding any liquid secretion; MGYCLS = meibomian glands yielding clear liquid secretion

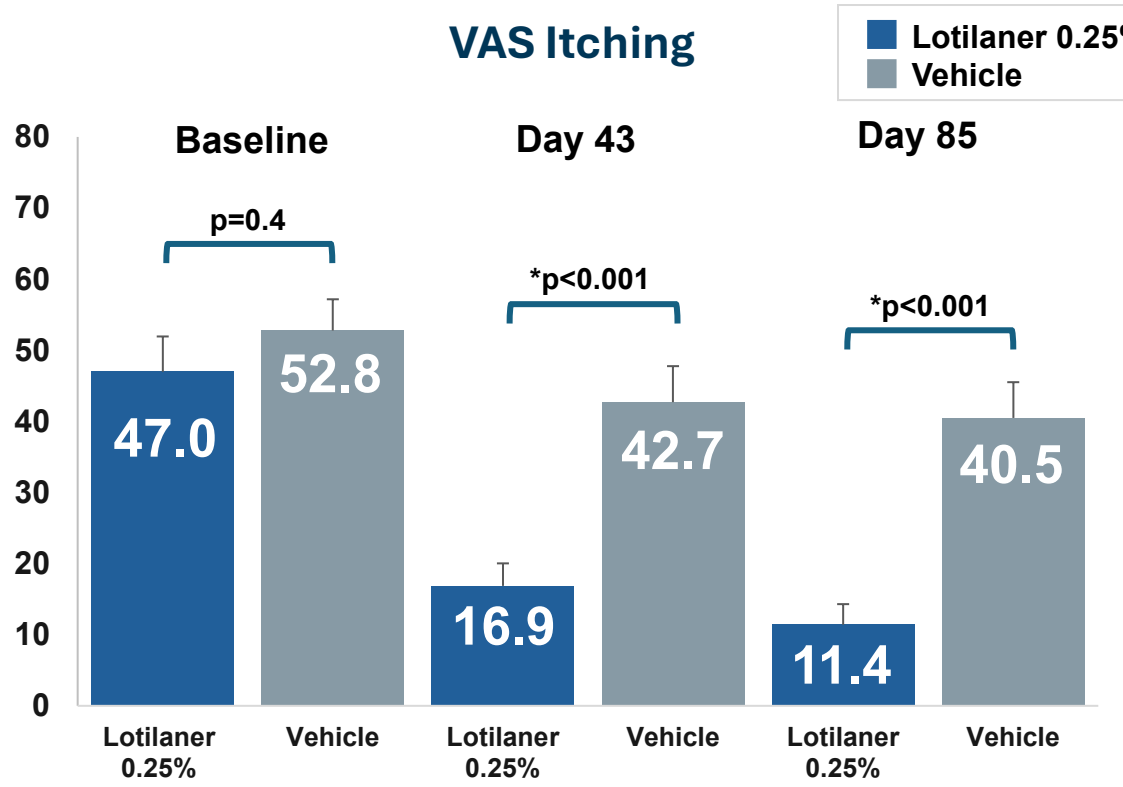
Lotilaner 0.25% demonstrated significant improvements in Patient-Reported Fluctuating Vision and Itching at 6 and 12 weeks

VAS Fluctuating Vision



N	39	40	38	34	38	33
p-value†			<0.001	0.010	<0.001	<0.001
Mean Δ			-23	-13	-32	-23

VAS Itching

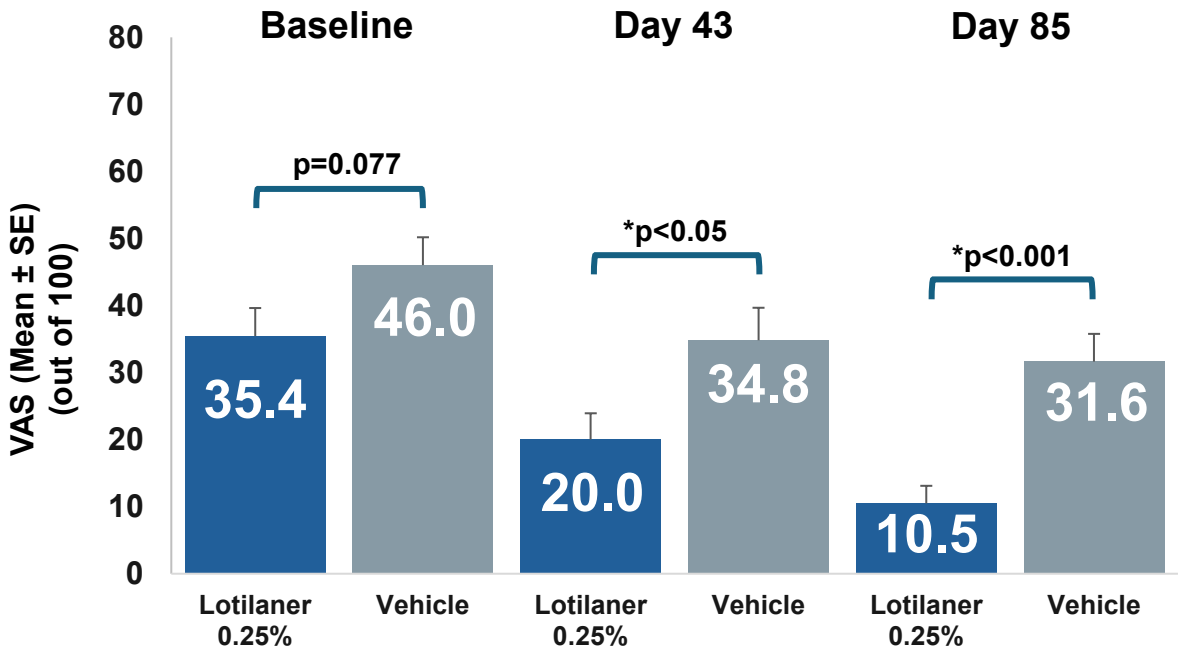


N	39	40	38	34	38	33
p-value†			<0.001	0.2	<0.001	0.13
Mean Δ			-30	-6.2	-35	-8.6

*Statistically significant †Paired t-test from baseline
VAS = visual analog scale

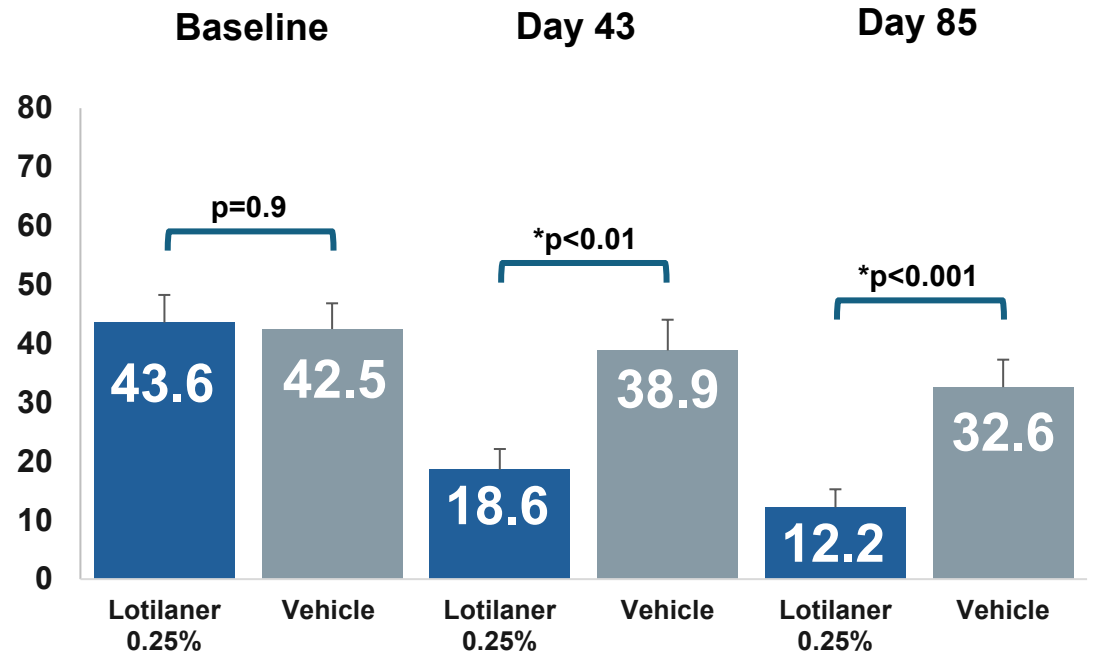
Lotilaner 0.25% demonstrated significant improvements in Patient-Reported Burning and Redness at 6 and 12 weeks

VAS Burning



N	39	40	38	34	38	33
p-value†			0.005	0.074	<0.001	0.030
Mean Δ			-15	-9.4	-25	-12

VAS Redness



N	39	40	38	34	38	33
p-value†			<0.001	0.5	<0.001	0.032
Mean Δ			-25	-3.7	-31	-11

*Statistically significant †Paired t-test from baseline
VAS = visual analog scale

Lotilaner 0.25% was well tolerated with a similar safety profile as the vehicle group

- **No serious treatment-related adverse events were observed in either study**

	ERSA: Lotilaner ophthalmic solution 0.25% (N=39)	RHEA: Vehicle (N=40)
Patients with ≥1 treatment-related AEs*, n (%)	2 (5.1)	7 (17.5)
Conjunctival irritation	0	1 (2.5)
Conjunctivitis	1 (2.6)	0
Dry eye	0	1 (2.5)
Eye irritation	0	1 (2.5)
Instillation site irritation	0	1 (2.5)
Noninfective conjunctivitis	0	1 (2.5)
Ocular discomfort	1 (2.6)	0
Ocular hyperemia	0	1 (2.5)
Punctate keratitis	0	2 (5.0)
Visual acuity reduced	0	1 (2.5)

AE: Adverse event; *Patients may have reported >1 AE.

Conclusions

- Lotilaner ophthalmic solution 0.25% demonstrated statistically significant improvements in measures of meibum quality, meibomian gland function, and patient-reported outcomes at 6 and 12 weeks compared to baseline and to vehicle.

- Lotilaner ophthalmic solution 0.25% was well tolerated with a similar safety profile as the vehicle group.

Eligibility Criteria

- ERSA and RHEA had the same eligibility criteria:

INCLUSION CRITERIA	
Demographics	Male or female ≥18 years of age
Meibomian gland disease	**The following 4 criteria in 1 eye:** ▪ Total meibomian gland secretion score between 12 and 32 ▪ Grade ≥1 lower eyelid erythema ▪ Tear break-up time <10 seconds ▪ Intact partial to full meibomian glands in ≥33% of meibomian gland area
Evidence of mite infestation	**The following 2 criteria in the same eye as above:** ▪ >10 eyelashes with collarettes ▪ ≥1 mite present based on examination of epilated lashes from the upper and lower eyelid
Symptoms	Visual analog scale (VAS, 0–100) score of >40 within 1 week of study Day 1 for eye dryness, ocular discomfort, fluctuating vision, burning, itching, or redness

EXCLUSION CRITERIA	
Excluded	Before or during the study: • Artificial tear use • Systemic antihistamine • Isotretinoin • Topical cyclosporine or lifitegrast • Topical prostaglandin analog • Blepharitis treatment (e.g., tea tree oil, lid scrubs, warm compresses, lid massage) • Meibomian gland disease treatment (e.g., LipiFlow®, intense pulsed light) **Each product had drug-specific restrictions for wash-out times before the treatment period or before study visits**