COURSE SYLLABUS

THE SUNCOAST SEMINAR

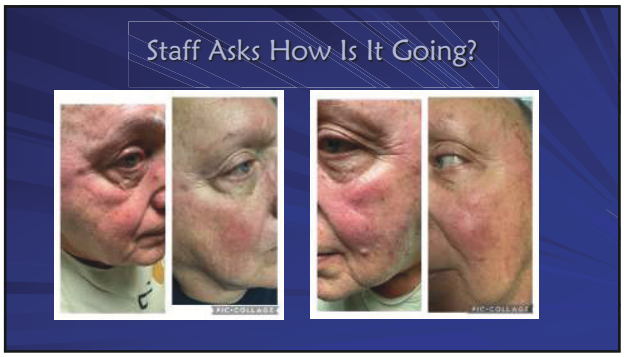
PRESENTED BY THE PINELLAS OPTOMETRIC ASSOCIATION

Saturday April 25

7:45 am - 8:15 am	**Registration**
	Exhibit Hall Open
	Continental breakfast - *sponsored by St. Luke's Cataract and Laser Institute*
8:15 am - 9:55 am	**Advances in Cornea, Cataract, Refractive and Glaucoma Surgery (2, TQ, COPE: 103831-GO)** Neel R. Desai, M.D. and Priti Panchal, O.D.
9:55 am - 10:40 am	**Break**
	Exhibit Hall Open
10:40 am - 12:20 pm	**Amblyopia Management for Primary Care O.D.s (1, COPE: 103274-FV)** **Acquired Brain Injury: What the O.D. Needs to Know (1, COPE: 103273-FV)** Richard Sorkin, O.D.
12:20 pm - 1:10 pm	**Lunch** - *sponsored by Retina Vitreous Associates of Florida*
	Exhibit Hall Open
1:10 pm - 1:20 pm	**Lighthouse of Pinellas Update**
1:20 pm - 1:30 pm	**FOA Update**
1:30 pm - 3:10 pm	**Pharmaceutical Update - Innovations and Insights for Eye Care (2, TQ, COPE: 103324-PH)** Greg Caldwell, O.D.
3:10 pm - 3:30 pm	**Break**
3:30 pm - 5:10 pm	**Latest Advances in Eye Care Technology - Innovations in Early Detection and Management (2, TQ, COPE:103700-GO)** Greg Caldwell, O.D.

Sunday April 26

7:30 am - 8:00 am	**Registration**
	Continental breakfast - *sponsored by the POA*
8:00 am - 9:40 am	**Grand Rounds - Improving Eye Care and Outcomes for Patients (2, TQ, COPE: 103866-TD)** Greg Caldwell, O.D.
9:40 am - 10:00 am	**Break**
10:00 am - 11:40 am	**Prevention of Medical Errors (2, COPE: 102834-EJ)** Alice Sterling, O.D.
11:40 am - 12:00 pm	**Lunch** - *sponsored by LENZ Therapeutics*
12:00 pm - 1:40 pm	**Florida Jurisprudence (2, COPE: 101024-EJ)** Alice Sterling, O.D



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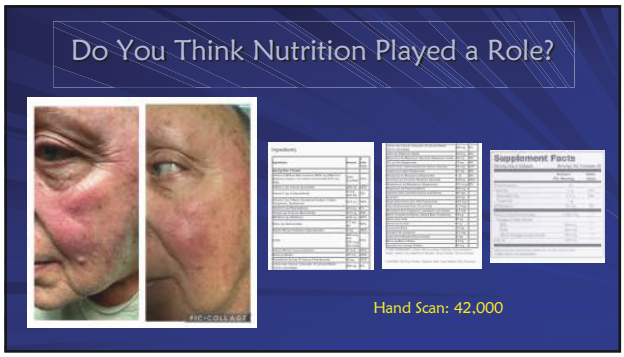

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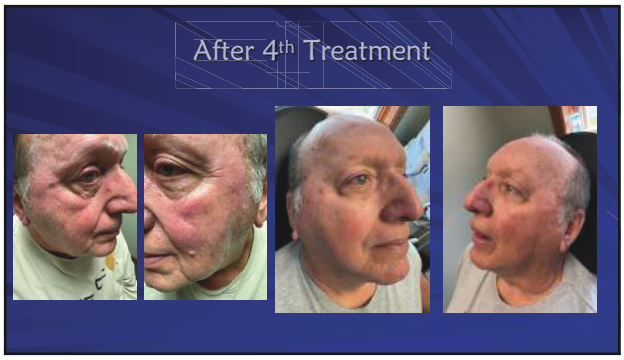

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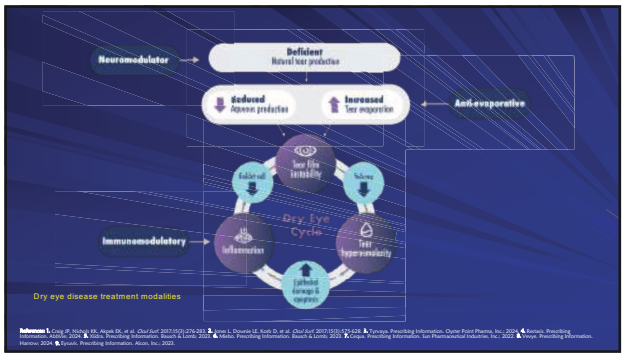

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What is the Lacrimal Functional Unit?

LFU

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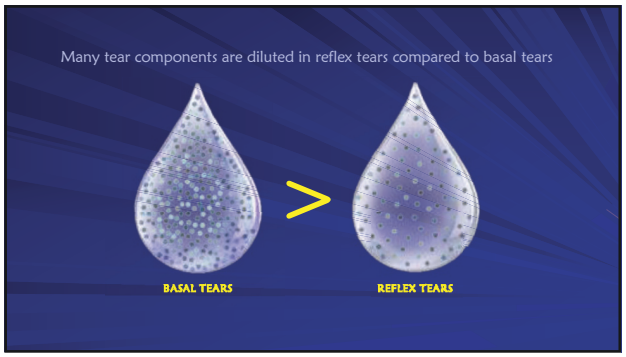

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Tryptyr (Acoltremon) Ophthalmic Solution 0.003%

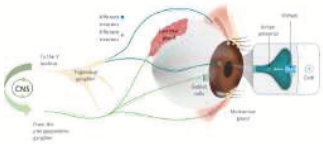
A drug candidate containing acoltremon, a TRPM8 agonist

WHAT IS TRPM8?

- Transient receptor potential melastatin 8 (TRPM8)
- Expressed on trigeminal sensory nerve terminals in corneal epithelium
- **Principal cold-sensitive TRP receptor**[1,2]

WHY TRPM8 AS A TARGET FOR DRY EYE?

- TRPM8 receptors are stimulated by ocular surface cooling and increased tear osmolarity associated with tear evaporation to regulate basal tear production[3-6]



1. Guerrero-Moreno A, Baudouin C, Melik Parsadaniantz S, Réaux-Le Goazigo A. *Front Cell Neurosci*. 2020;14:610342. 2. McCoy DD, Knowlton WM, McKemy DD. *Am J Physiol Regul Integr Comp Physiol*. 2011;300(6):R1278-R1287. 3. Hirata H and Meng ID. *Invest. Ophthalmol. Vis. Sci.* 2010;51(8):3969-3976; 4. Belmonte C, Gallar J. *Invest Ophthalmol Vis Sci*. 2011;52(6):3888-3892. 5. Parra A, Madrid R, Echevarria D, et al. *Nat Med*. 2010;16(12):1396-1399. 6. Quallo T, Vastani N, Horridge E et al. *Nat Commun*. 2015; 6: 7150.

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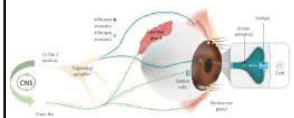
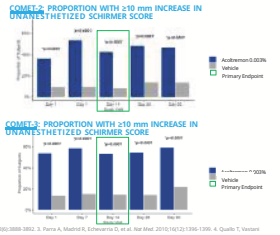
Tryptyr (Acoltremon) Ophthalmic Solution 0.003%

Acoltremon is a potent and selective TRPM8 agonist that activates the trigeminal nerve to stimulate tear production



- Transient receptor potential melastatin 8 (TRPM8) receptors are expressed on trigeminal sensory nerve terminals in corneal epithelium
- TRPM8 receptors are stimulated by ocular surface cooling and increased tear osmolarity associated with tear evaporation to regulate basal tear production[1-4]

Primary endpoint met in both phase 3 (COMET) trials



1. Hirata H and Meng ID. *Invest. Ophthalmol. Vis. Sci.* 2010;51(8):3969-3976; 2. Belmonte C, Gallar J. *Invest Ophthalmol Vis Sci*. 2011;52(6):3888-3892. 3. Parra A, Madrid R, Echevarria D, et al. *Nat Med*. 2010;16(12):1396-1399. 4. Quallo T, Vastani N, Horridge E et al. *Nat Commun*. 2015; 6: 7150.

Acoltremon ophthalmic solution 0.003% is an investigational drug that has not been approved for any indication in any country; therefore, its safety and efficacy have not been established.

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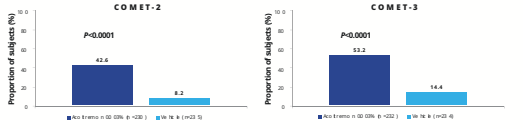
Acoltremon 0.003% Met the Primary Endpoint in Both Pivotal Studies

- Proportion differences were 34.4% (*P*<0.0001) and 38.8% (*P*<0.0001) for COMET-2 and COMET-3, respectively
- In the pooled analysis, the proportion of subjects who achieved a ≥10-mm increase in unanesthetized Schirmer score at day 14 was 47.9% for acoltremon 0.003% vs 11.4% for vehicle groups, respectively, yielding a difference of 36.5% (*P*<0.0001)

Proportion of subjects who achieved a ≥10-mm improvement from baseline in unanesthetized Schirmer score on day 14



Acoltremon ophthalmic solution 0.003% is an investigational drug that has not been approved for any indication in any country; therefore, its safety and efficacy have not been established.

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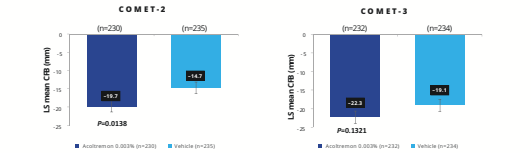
First (Key) Secondary Endpoint: Change From Baseline in SANDE Score on Day 28

Met in COMET-2 (P=0.0138); numerically greater with acoltremon 0.003% in COMET-3 (P=0.1321)

Change from baseline in SANDE score on day 28



CFB, change from baseline; LS, least squares; SANDE, Symptom Assessment IN Dry Eye (0-100, where 100 is most severe).

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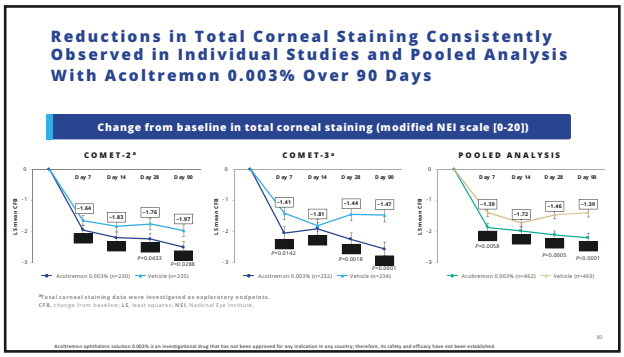

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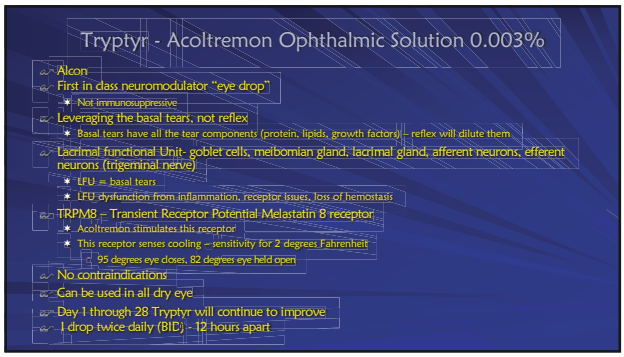

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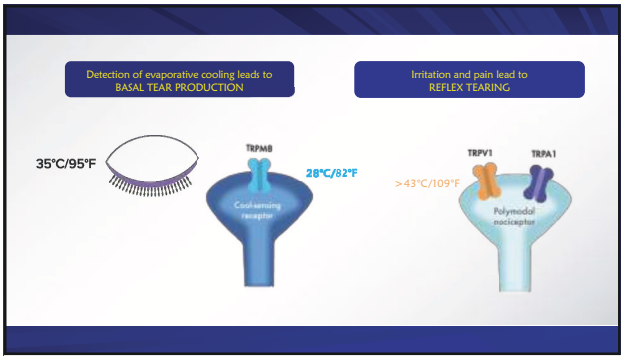

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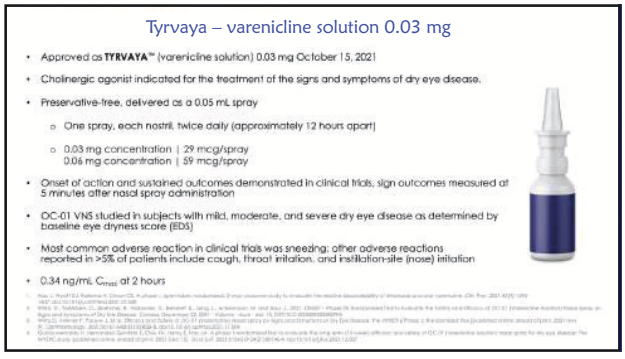

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Miebo (perfluorohexyloctane ophthalmic solution) 100%

- Bausch & Lomb
- May 18, 2023 – approved
- Indication: treatment of the signs and symptoms of dry eye disease (DED)
- Unique characteristics: water-free, non-steroidal, single-component preservative-free eye drop formulated with 100% perfluorohexyloctane to treat DED
- Mechanism of actions:
  - Spreads rapidly across the ocular surface due to its low surface tension then interacts with the lipophilic portion of the tear film that prevents tear evaporation
  - Can penetrate the meibomian glands, where it interacts with and dissolves altered, viscous meibum in the glands
- Administration: Drops
- Dosing: 1 gtt QID into each eye

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Miebo (perfluorohexyloctane ophthalmic solution) 100% Unique Characteristics

- Single-ingredient formulation
- No inactive ingredients
- Water free
- Preservative free
- Mimics key functions of natural meibum
- Forms a monolayer at the air-tear interface = reduced evaporation
- Remains in the tears up to 6 hours
- 11 microliter drop

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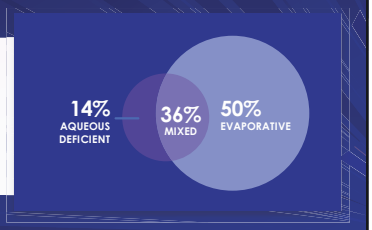
The Majority of DED Has an Evaporative Etiology

MGD, the major contributor to the evaporative etiology of DED, is present in ≥86% of cases[1-3]



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Excessive Evaporation Triggers A Vicious Cycle

When tear evaporation exceeds supply, loss of homeostasis follows

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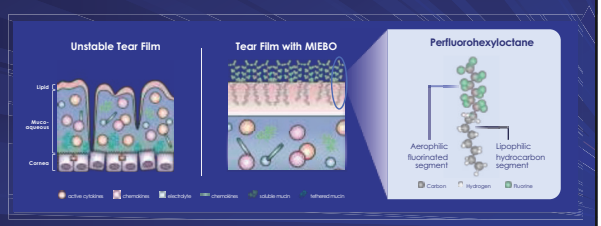
MIEBO Forms A Monolayer at the Air-liquid Interface



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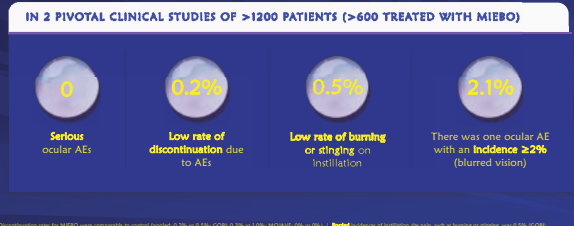
An Excellent Tolerability Profile

IN 2 PIVOTAL CLINICAL STUDIES OF >1200 PATIENTS (>600 TREATED WITH MIEBO)



Discontinuation rate for MIEBO were comparable to control (pooled: 0.2% vs 0.5%; GOBI: 0.3% vs 1.0%; MOJAVE: 0% vs 0%). | Pooled incidences of instillation site pain, such as burning or stinging, was 0.5% (GOBI: 1.0%; MOJAVE: 0%). | The most common ocular AE was blurred vision, which was mostly mild and transient. Blurred vision (pooled: 2.1%; GOBI: 3.0%; MOJAVE: 1.3%) and conjunctival redness (pooled: 0.8%; GOBI: 0%; MOJAVE: 1.3%) were reported in 1%-3% of individuals

1. Tauber J, et al. Ophthalmology. 2022;130(5):516-524. 2. Sheppard JD, et al. Am J Ophthalmol. 2023;252:265-274. 3. Data on File. Bausch + Lomb Incorporated.
AE, adverse event

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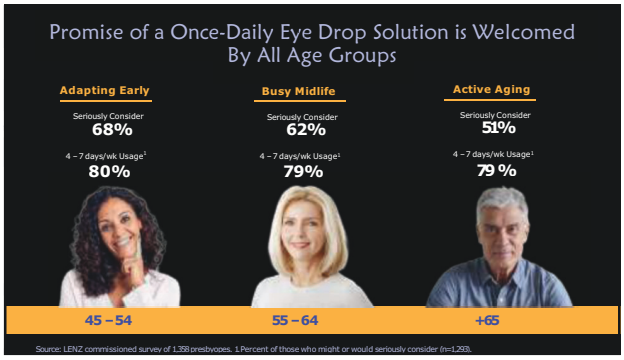

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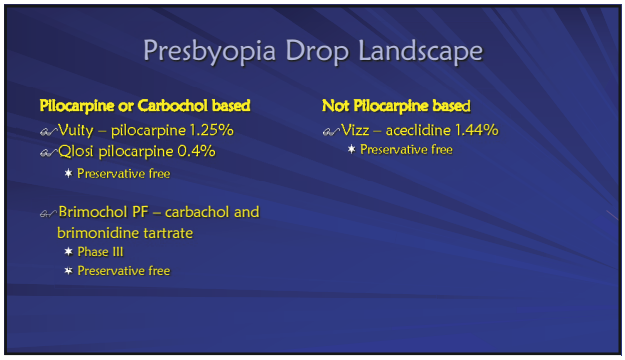

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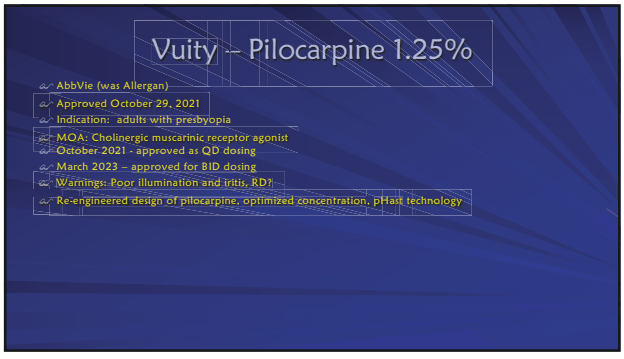

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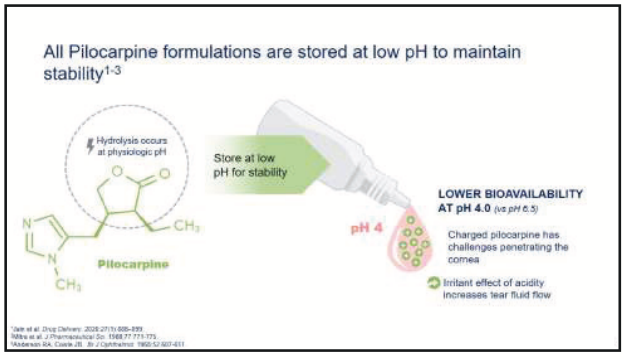

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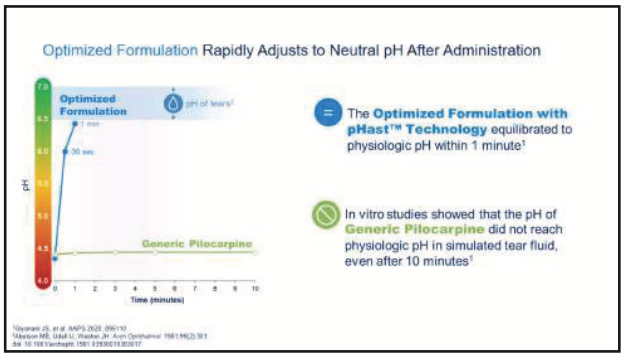

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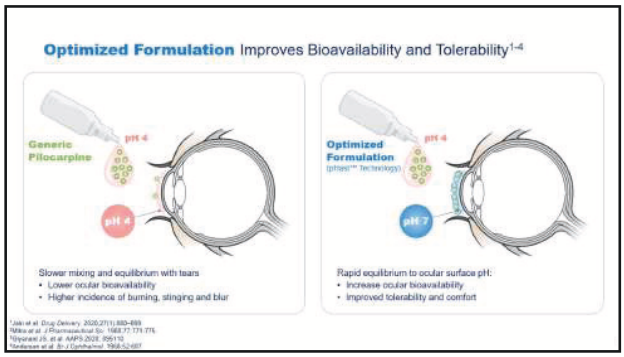

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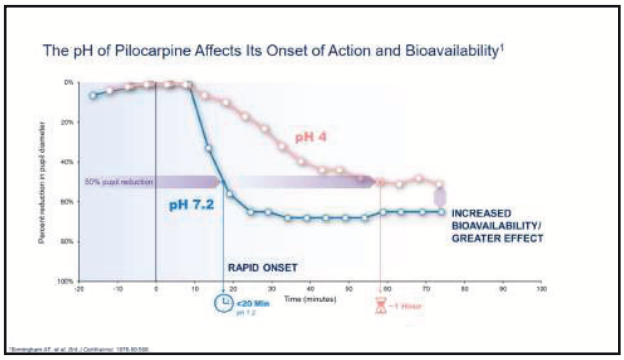

100

Qlosi (pilocarpine hydrochloride ophthalmic solution) 0.4%

- Orasis Pharmaceuticals
- October 2023 – approval
- Pronounced: CLOH-see
- Indication: Treatment of presbyopia
- Dosing: one drop in each eye can be used daily or as needed
  - Dosing up to twice a day, 2 to 3 hours apart
- Low dose pilocarpine

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Vizz - Aceclidine Ophthalmic Solution 1.44% Not Pilocarpine based

- Lenz Therapeutics
- FDA approved July 31, 2025
- Not pilocarpine
- New MOA and twist to MOD
- Once a day "Dosing"
  - Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily from the same single dose vial
- Achieves <2 mm pupil size
  - Clarification vs magnification
- Can write scripts 8-14-2025, shipping approximately 10-15-2025
- Only ECP able to Rx
- Sample will be available for the patient to try first

102

Vizz - Aceclidine Ophthalmic Solution 1.44%

- Broad population in clinical trials
  - Age 45-75 years (mean 55 years)
    - Maximum age for Vuity was 54.5 years
  - Included post-LASIK/PRK and pseudophakia
- Long term safety data, since a new molecule
  - Vuity – did not have to do, since there was data on pilocarpine
- Check near vision with distance correction – if 20/50 or worse = good candidate
  - Don't recommend going by age
- Achieved 20/40 near for 10 hours in 7/10 patients
- Works fast – 30 minutes

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Vizz - Aceclidine Ophthalmic Solution 1.44%

- Adverse Events
  - Installation site irritation 20% 99% mild
  - Dim vision 16% 92% mild
  - Hyperemia 15% 98% mild
  - Headache 13% 81% mild
- Headache
  - Not a pilocarpine HA
  - 81% mild (no ibuprofen needed)
  - 33% no longer reported after day 2, 44% no longer reported after day 7
  - Resolved by day 28

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Vizz - Aceclidine Ophthalmic Solution 1.44%

	Iris sphincter 50% constriction (nmol/L)	Ciliary muscle 50% constriction (nmol/L)	Iris selectivity
Aceclidine	900	25,000 longitudinal 20,000 circular	> 20:1 Smaller pupil
Pilocarpine	1800	3,360 longitudinal 2,840 circular	< 2:1 Larger pupil

Works via pupil constriction and spares the ciliary body

105

Vizz - Aceclidine Ophthalmic Solution 1.44%

- Aceclidine
  - -0.17 diopters (myopia)
  - 0.078 mm lens shift
  - 0.07 mm increase in lens thickness
- Pilocarpine
  - -1.3 diopters (myopia)
  - 0.234 mm lens shift
  - 0.2 mm increase in lens thickness

106

Vizz - Aceclidine Ophthalmic Solution 1.44%

- Aceclidine
  - -0.17 diopters (myopia)
  - 0.078 mm lens shift
  - 0.07 mm increase in lens thickness
- Pilocarpine
  - -1.3 diopters (myopia)
  - 0.234 mm lens shift
  - 0.2 mm increase in lens thickness

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Vizz - Aceclidine Ophthalmic Solution 1.44%

- How to prescribe
  - Quality 25 vials (most use 5 days/week)
  - Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily from the same single dose vial (not BID, this is a single dose)
  - Refills 14
  - Notes: Pharmacist authorized to adjust quantity dispensed per patient request not to exceed year supply
- UpScript Pharmacy
  - Free home delivery
- Can use local pharmacy – cost not controlled
- Cash only = no prior authorization
- HAS/FSA eligible
- Cost
  - $79 – 1 month supply (25 vials)
  - $198 – 3 months ($66/month)

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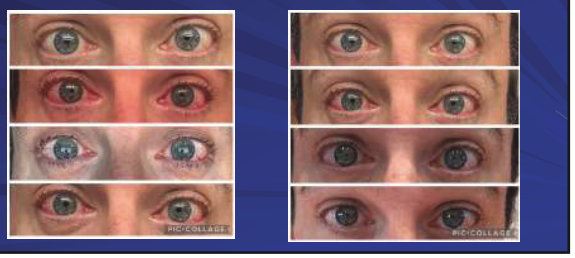
Vizz - Aceclidine Ophthalmic Solution 1.44%

2 minutes after installation
first day, day 4, day 5

30 minutes after installation
first day, day 4, day 5



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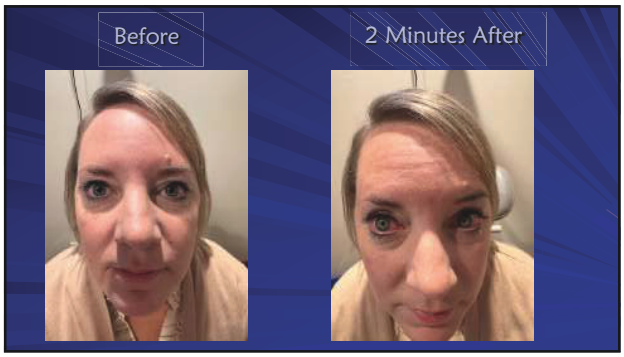

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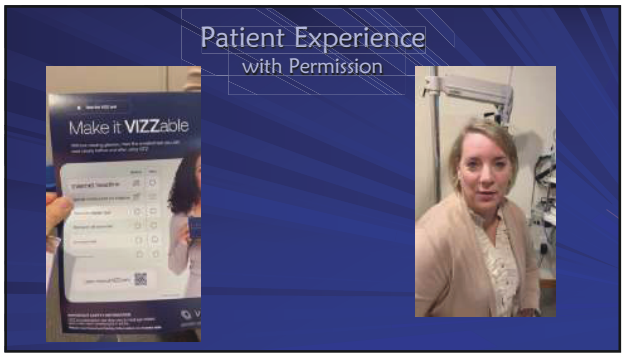

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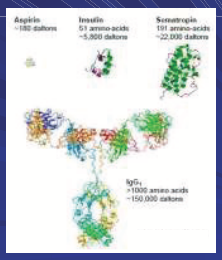
Biologic Drugs versus Small Molecule Drugs

- Biologic Drugs
  - Larger, complex, dynamic structures
  - Diverse populations of molecules
    - Not easily characterized
  - Complicated manufacturing
  - Example: Teprotumumab (Tepezza)
- Small Molecule Drugs
  - Synthetic
  - Manufactured using a defined chemical process
  - Smaller and simpler
  - Example: Aspirin



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Why Your Patients Are on ELAHERE

Eye Care Considerations for Patients Treated With ELAHERE

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Optometry's role with Elehere - Mirvetuximab Soravtansine gynx (MIRV)

- Antibody-drug conjugate (ADC) comprising an FR-binding antibody, cleavable linker, and maytansinoid DM4 payload
- Primary ocular events with MIRV include corneal disorder, corneal epithelial defect, keratitis, keratopathy, corneal deposits, and punctuate keratitis
- Exam and clear patient for treatment

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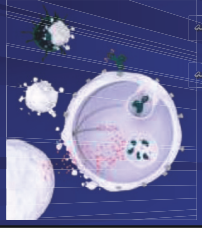
Elehere - Mirvetuximab Soravtansine

Mirvetuximab soravtansine (MIRV) is the first biomarker-directed agent showing antitumor activity in patients with FRα-positive[a] platinum-resistant ovarian cancer (PROC)[1]

- MIRV is an antibody-drug conjugate (ADC) comprising an FRα-binding antibody, cleavable linker, and maytansinoid DM4 payload
- A phase 3 clinical study, SORAYA, evaluated MIRV in patients with FRα high PROC who had received 1 to 3 prior therapies, including required bevacizumab



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Why Your Patients Are on ELAHERE

ELAHERE is a therapy approved to treat certain patients with advanced ovarian cancer

- ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FR) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Who have received one to three prior systemic treatment regimens
- This indication is approved under accelerated approval based on tumor response rate and durability of response

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Why Eye Care Is Important for Patients Receiving ELAHERE™

You play a critical role in patient management as ocular adverse events have been observed in patients treated with ELAHERE

BOXED WARNING: OCULAR TOXICITY

- **ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue ELAHERE for Grade 4 ocular toxicities.**

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Proposed MOA for Ocular Events Associated With MIRV

- The underlying mechanisms of ocular toxicities remain poorly understood, but it is hypothesized to be an off-target effect on the corneal epithelium due to the lack of FRα receptors in that part of the eye
- Anti-microtubule payloads such as DM4 have been previously associated with resolvable ocular toxicity, such as blurred vision, dry eye, and keratopathy
- One hypothesis for toxicity seen with anti-microtubule payloads is that symptoms arise from a change in curvature of the cornea due to transient alterations in corneal epithelial thickness or corneal biomechanical properties, associated with the presence of microcysts
- Additionally, prolonged retention in circulation associated with MIRV's stable linker may lead to enhance exposure in normal tissues

The ocular AE profile of MIRV is a dose-dependent toxicity limited to the corneal epithelium of the eye, with resolvability observed in both non-clinical and human studies

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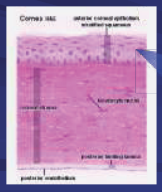
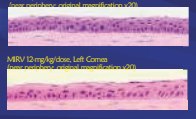
Microscopic Analysis of the Corneal Epithelium



Non-clinical Microscopic Analysis
(Control and MIRV 12-mg/kg Dose)[1]



Control, Left Cornea

MIRV 12-mg/kg dose, Left Cornea

Key Observations With MIRV 12-mg/kg Dose

- **Fewer and larger** epithelial cells
- Overall **thinner** epithelial layer
- Basal layer appearing disorganized as **gaps** noted between visible nuclei
- **No visible nuclei** in places across the thickness of the epithelial layer, suggesting no cells other than those of the basal layer were present
- **Lesions only** at the periphery of the cornea

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Due to the Possibility of Ocular Adverse Events With ELAHERE Eye Care Is Necessary

- Ophthalmic Exams
- Preventive Measures
- Lubricating Eye Drops
- Ophthalmic Topical Steroids

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Proactive Management of Ocular Adverse Events

- Patients should receive a baseline ophthalmic exam from an ophthalmologist or optometrist prior to treatment initiation and follow-up exams during every other cycle for the first 8 cycles, and as clinically indicated
- Tell patients to avoid use of contact lenses, unless they are medically necessary
- Use of preservative-free[a] lubricating eye drops at least 4 times daily and as needed is recommended during treatment with ELAHERE
- Use of ophthalmic topical corticosteroids is recommended
  - The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp

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Recommended Schedule for Eye Drops

Ophthalmic Topical Corticosteroids

Starting the day before ELAHERE infusion until 3 days after infusion (Days 1–4)

- Advise patients to apply 1 drop in each eye 6 times daily

On Days 5–8

- Advise patients to apply 1 drop in each eye 4 times daily

Lubricating Eye Drops

The use of preservative-free lubricating eye drops is also recommended at least 4 times daily and as needed during treatment. Advise patients to wait at least 10 minutes after administering ophthalmic topical corticosteroids before using lubricating eye drops

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What to Look for in the Baseline Ophthalmic Exam

- A baseline ophthalmic examination should include a visual acuity test and slit lamp exam
- Document the patient's current symptoms and visual acuity prior to the initiation of ELAHERE™

Symptom Assessment

Inquire about ocular symptoms (eg, vision impairments, dry eye, photophobia, eye pain), and treat as appropriate

Visual Acuity

Measure best corrected visual acuity at baseline to help understand whether changes have occurred during follow-up exams

Slit Lamp Exam

Assess corneal health (eg, keratopathy, superficial punctate keratitis) is recommended before initiation of treatment with ELAHERE

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What to Monitor During Scheduled Follow-up Ophthalmic Exams

Monitor patients every other cycle (~every 6 weeks) for the first 8 cycles (~6 months) of ELAHERE™ for any changes from the baseline ophthalmic exam, and as clinically indicated[1]

Symptom Assessment[1]

- Inquire about any new or worsening ocular symptoms since the most recent ophthalmic exam

Visual Acuity[1]

- Compare against baseline measurement to determine whether best corrected visual acuity has changed

Slit Lamp Exam[1]

- Document any ocular findings, including keratopathy and uveitis

Note: As part of their treatment with ELAHERE, your patient is being prescribed ophthalmic topical steroids that may elevate intraocular pressure

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Presentation of Keratopathy (Microcyst-like Corneal Epithelial Changes)

- Microcyst-like corneal epithelial changes (MECs) may be identified during ophthalmic slit lamp exams[1]
- MECs can appear in both symptomatic and asymptomatic patients[2]
- Document whether MECs are[3]:
  - Confluent (ie, merging or clumped)
  - Nonconfluent (ie, separated or distinct)

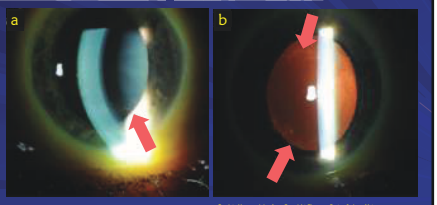

Figure. Arrows denote corneal microcysts observed in a 69-year-old patient 5 weeks after receiving ELAHERE™.[1]

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What to Expect With Ocular Events Associated With ELAHERE™

Integrated Safety Analysis of Patients Treated With ELAHERE (N=464)[4]

Timing of Onset

- Median onset to the first ocular adverse event was ~3 weeks (range, 1 day–55.3 weeks)[1]

Impact

- Ocular adverse events of any grade occurred in 61% of patients[1]
  - Grade 1 or 2: >90% of patients
  - Grade 3: 9% of patients
  - Grade 4: 0.2% of patients[a]

Resolution

- No patients had permanent ocular sequelae[2]
- Ocular adverse events led to permanent discontinuation of ELAHERE in 0.6% of patients[1]

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Monitoring Ocular Adverse Events

Ophthalmic Exam Findings Requiring Dose Modifications

Ophthalmic exam finding	Severity of finding	Action
Keratitis/ keratopathy	Nonconfluent superficial keratitis	Monitor
	Confluent superficial keratitis, a cornea epithelial defect, or 3-line or more loss in best corrected visual acuity	Notify treating oncologist[a]
	Corneal ulcer or stromal opacity or best corrected distance visual acuity of 20/200 or worse	
	Corneal perforation	
Uveitis	Grade 1/rare cell in anterior chamber	Monitor
	Grade 2/1-2+ cell or flare in anterior chamber	
	Grade 3/3+ cell or flare in anterior chamber	Notify treating oncologist[a]
	Grade 4/hypopyon	

Ocular adverse events should be treated by the eye care provider per standard clinical guidelines

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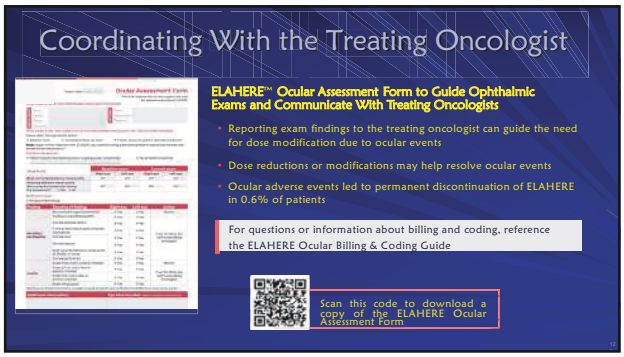
Coordinating With the Treating Oncologist
ELAHERE™ Ocular Assessment Form to Guide Ophthalmic Exams and Communicate With Treating Oncologists
Reporting exam findings to the treating oncologist can guide the need for dose modification due to ocular events
Dose reductions or modifications may help resolve ocular events
Ocular adverse events led to permanent discontinuation of ELAHERE in 0.6% of patients
For questions or information about billing and coding, reference the ELAHERE Ocular Billing & Coding Guide
Scan this code to download a copy of the ELAHERE Ocular Assessment Form

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Optometric Education Consultants
Questions and Thank You!
Pharmaceutical Update
Innovations and Insights for Eye Care
Greg Caldwell, OD, FAAO
The Suncoast Seminar
April 25-26, 2026

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