

COURSE SYLLABUS

20/100

T

H E

20/70

S U N

20/50

C O A S T

20/40

S E M I N A R

20/25

F O R O P T O M E T R Y

20/20

A P R I L 2 5 - 2 6 , 2 0 2 6

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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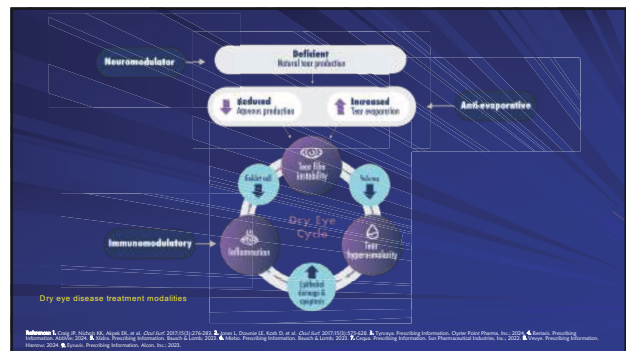
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72



73

What is the Lacrimal Functional Unit?

LFU

74

Many tear components are diluted in reflex tears compared to basal tears

BASAL TEARS > **REFLEX TEARS**

75

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^{3,4}

1. Yamanaka and Meng (2015) Invest Ophthalmol Vis Sci. 56(10):3040-3050. 2. Behremani C, Geller J. Invest Ophthalmol Vis Sci. 2015;56(10):3040-3050. 3. Parva A, Mahesh S, Srinivasan S, et al. Invest Ophthalmol Vis Sci. 2015;56(10):3040-3050. 4. Quillo T, Vazquez R, et al. Invest Ophthalmol Vis Sci. 2015;56(10):3040-3050.

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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

Primary endpoint met in both phase 3 (COMET) trials

COMET-2: PROPORTION WITH ≥10 mm INCREASE IN DRYANESTHETIZED SCHIRMER SCORE

COMET-3: PROPORTION WITH ≥10 mm INCREASE IN DRYANESTHETIZED SCHIRMER SCORE

- 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}

1. Yamanaka and Meng (2015) Invest Ophthalmol Vis Sci. 56(10):3040-3050. 2. Behremani C, Geller J. Invest Ophthalmol Vis Sci. 2015;56(10):3040-3050. 3. Parva A, Mahesh S, Srinivasan S, et al. Invest Ophthalmol Vis Sci. 2015;56(10):3040-3050. 4. Quillo T, Vazquez R, et al. Invest Ophthalmol Vis Sci. 2015;56(10):3040-3050.

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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

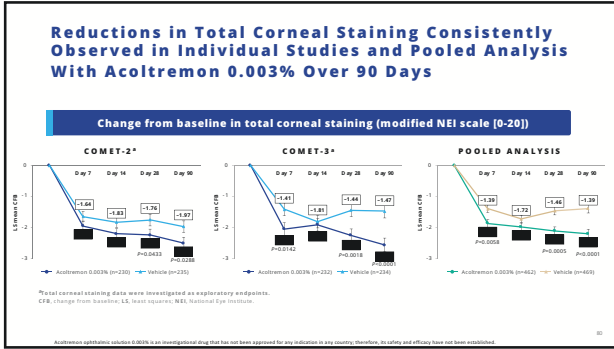
Met in COMET-2 (P=0.0138); numerically greater with acoltremon 0.003% in COMET-3 (P=0.1321)

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).

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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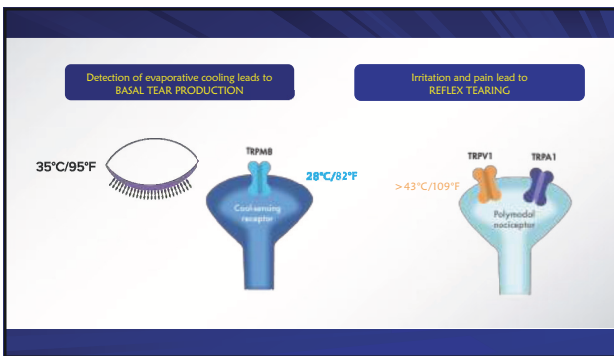


80

Tryptyr - Acotremon Ophthalmic Solution 0.003%

- Alcon
- First in class neuromodulator "eye drop"
 - Not immunosuppressive
 - Leveraging the basal tears, not reflex
 - Basal tears have all the tear components (protein, lipids, growth factors) - reflex will dilute them
- Lacrimal functional Unit- goblet cells, meibomian gland, lacrimal gland, afferent neurons, efferent neurons (trigeminal nerve)
 - LPU = basal tears
 - LPU dysfunction from inflammation, receptor issues, loss of hemostasis
- TRPM8 - Transient Receptor Potential-Melastatin 8 receptor
 - Acotremon stimulates this receptor
 - This receptor senses cooling - sensitivity for 2 degrees Fahrenheit
 - 95 degrees eye closes, 82 degrees eye held open
- No contraindications
 - Can be used in all dry eye
 - Day 1 through 28 Tryptyr will continue to improve
 - 1 drop twice daily (BID) - 12 hours apart

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Tryptyr - Acotremon Ophthalmic Solution 0.003%

Need to rethink dry eye treatment - not directly treating the inflammation of dry eye

Inflammation

Basal tear production

Reflex tearing

Ant-epoxythene

CNS

Eye

83

Tyrvaya - varenicline solution 0.03 mg

- October 21, 2021 - Viatris
- Nasal spray
- BID - approximately every 12 hours
- Preservative-free
- 1/33 of dosage of Chantix
 - Depression
 - Smoking cessation

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Tyrvaya - varenicline solution 0.03 mg

- Approved as **TYRVAYA™** (varenicline solution) 0.03 mg October 15, 2021
- Cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease.
- Preservative-free, delivered as a 0.05 mL spray
 - One spray, each nostril, twice daily (approximately 12 hours apart)
 - 0.03 mg concentration | 29 mcg/spray
 - 0.06 mg concentration | 59 mcg/spray
- Onset of action and sustained outcomes demonstrated in clinical trials, sign outcomes measured at 5 minutes after nasal spray administration
- OC-01 VNS studied in subjects with mild, moderate, and severe dry eye disease as determined by baseline eye dryness score (EDS)
- Most common adverse reaction in clinical trials was sneezing; other adverse reactions reported in >5% of patients include cough, throat irritation, and irritation-site (nose) irritation
- 0.34 ng/mL C_{max} at 2 hours

85

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

87

The Majority of DED Has an Evaporative Etiology

MGD, the major contributor to the evaporative etiology of DED, is present in ≥86% of cases¹⁻³

Etiology	Percentage
Aqueous Deficient	14%
Mixed	36%
Evaporative	50%

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Excessive Evaporation Triggers A Vicious Cycle

When tear evaporation exceeds supply, loss of homeostasis follows

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    graph LR
        A[LIPID, AQUEOUS, MUCIN DEFICIENCY  
LIFESTYLE, ENVIRONMENT, CITIES] --> B[EVAPORATION EXCEEDS TOTAL TEAR SUPPLY]
        B --> C[Desiccation Stress  
Tissue Damage  
Inflammation]
        C --> D[OCULAR SURFACE]
        D --> B
    
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MIEBO Forms A Monolayer at the Air-liquid Interface

Unstable Tear Film vs **Tear Film with MIEBO**

Perfluorohexyloctane structure: Aerophilic fluorinated segment, Lipophilic hydrocarbon segment.

90

An Excellent Tolerability Profile

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

- 0 Serious ocular AEs
- 0.2% Low rate of discontinuation due to AEs
- 0.5% Low rate of burning or stinging on instillation
- 2.1% There was one ocular AE with an incidence ≥2% (blurred vision)

Discontinuation rates for MIEBO were comparable to control (pooled: 0.2% vs 0.5%; GOE: 0.2% vs 0.6%; MCGAVE: 0% vs 0%). **Red** Incidence of instillation site pain, such as burning or stinging, was 0.5% (GOE: 0.6%; MCGAVE: 0%). The most common ocular AE was blurred vision, which was mostly mild and transient. Blurred vision (pooled: 2.1%; GOE: 2.0%; MCGAVE: 1.3%) and conjunctival redness (pooled: 0.8%; GOE: 0.8%; MCGAVE: 1.3%) were reported in 1%–2% of patients.

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MIEBO Offers a Comfortable Experience

In clinical studies, the majority of patients rated MIEBO as **COMFORTABLE OR VERY COMFORTABLE** on instillation*

Small drop size (11.4µl) means MIEBO may feel different from formulations containing water†

There may be no ocular sensation or blink reflex upon instillation

Contact lenses should be removed prior to and for at least 30 minutes after the administration of MIEBO.
*Instillation comfort was assessed via questionnaire given approximately 2 minutes after dosing on Day 1 of the GOBI and MQUAVE studies; it was scored on a visual analog scale from 0 to 100 being the most comfortable). Mean pooled comfort score was 8.0 for MIEBO and 8.4 for saline. 87% of patients treated with MIEBO reported a score of 7 or higher.
†Formulations containing water may have a typical drop size of 35 to 50 µl.

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Presbyopia This Market is Not Going Away Soon

- Presbyopia, the inevitable loss of near vision
- Research shows adults over 50 lose on average 15 lines of near vision per 6 years!
- Impacts **128 M** People in the US

Potential \$3B+ Market

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Promise of a Once-Daily Eye Drop Solution is Welcomed By All Age Groups

Adapting Early	Busy Midlife	Active Aging
Seriously Consider 68%	Seriously Consider 62%	Seriously Consider 51%
4-7 days/wk Usage ¹ 80%	4-7 days/wk Usage ¹ 79%	4-7 days/wk Usage ¹ 79%
45-54	55-64	+65

Source: LENZ commissioned survey of 1,339 presbyopes. 1. Percent of those who might or would seriously consider (n=1,203).

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Presbyopia Drop Landscape

Pilocarpine or Carbachol based	Not Pilocarpine based
<ul style="list-style-type: none"> Vuity – pilocarpine 1.25% Qloxi pilocarpine 0.4% * Preservative free 	<ul style="list-style-type: none"> Vizz – aceclidine 1.44% * Preservative free
<ul style="list-style-type: none"> Brimochol PF – carbachol and brimonidine tartrate * Phase III * Preservative free 	

95

Vuity – Pilocarpine 1.25%

- AbbVie (was Allergan)
- Approved October 29, 2021
- Indication: adults with presbyopia
- MOA: Cholinergic muscarinic receptor agonist
- October 2021 - approved as QD dosing
- March 2023 - approved for BID dosing
- Warnings: Poor illumination and iritis, RDI
- Re-engineered design of pilocarpine, optimized concentration, pHalk technology

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All Pilocarpine formulations are stored at low pH to maintain stability¹⁻³

Hydrolysis occurs at physiologic pH

Store at low pH for stability

LOWER BIOAVAILABILITY AT pH 4.0 (vs pH 6.5)

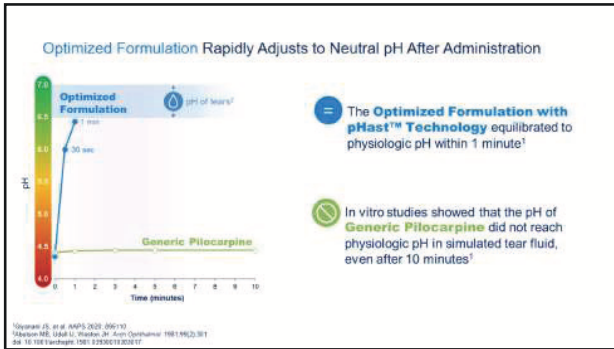
Charged pilocarpine has challenges penetrating the cornea

Irritant effect of acidity increases tear fluid flow

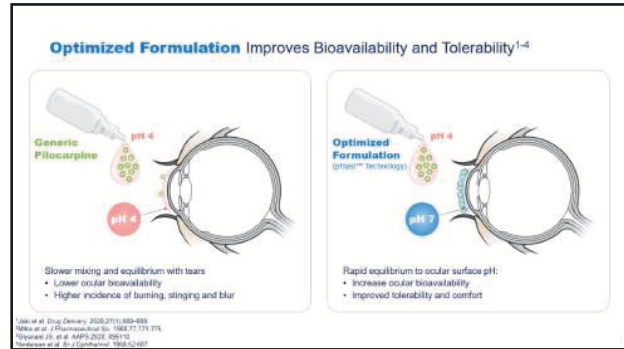
CN1C=NC=C1C2=CC=C(C)OC2

1. Sale et al. Drug Delivery. 2020;21(1):626-639.
2. Nishi et al. J Pharmaceutical Sci. 1988;77:773-775.
3. Henderson SA, Clarke JB. Br J Ophthalmol. 1992;66:267-271.

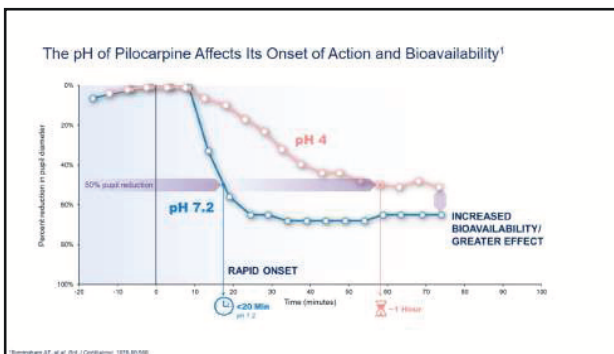
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100

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

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Vizz - Aceclidine Ophthalmic Solution 1.44%

- Broad population in clinical trials
 - ★ Age 45-75 years (mean 55 years)
 - Maximum age for Vuity was 64.5 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

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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%

- 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%

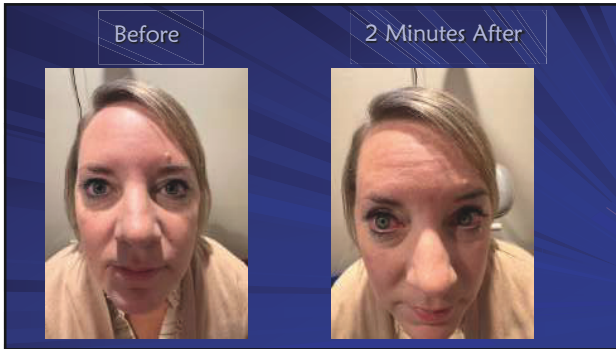
- How to prescribe**
 - Quality 25 vials (most use 5 days/week)
 - Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily from the same single dose vial (not BID, this is a single dose)
 - Refills 14
 - Notes: Pharmacist authorized to adjust quantity dispensed per 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 vial)
 - \$190 - 3 months (\$66/month)

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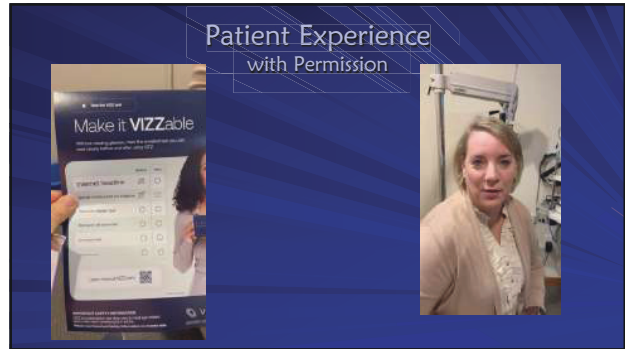
2 minutes after installation
first day, day 4, day 5

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

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Biologic Drugs versus Small Molecule Drugs

Drug	Aspirin	Insulin	Sertraline
Size	~180 Daltons	51 amino acids	101 amino acids
Complexity	~5,000 Daltons	~22,000 Daltons	>1000 amino acids

- 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 α -binding antibody, cleavable linker, and maytansinoid DM4 payload
- Primary ocular events with MIRV include corneal disorder, corneal epithelial defect, keratitis, keratopathy, corneal deposits, and punctate 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 FR α -positive⁺ platinum-resistant ovarian cancer (PROC)¹

- MIRV is an antibody-drug conjugate (ADC) comprising an FR α -binding antibody, cleavable linker, and maytansinoid DM4 payload
- A phase 3 clinical study, SORAYA, evaluated MIRV in patients with FR α -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 α) 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 FR α receptors in that part of the eye
- Antimicrotubule 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 microcyts
- 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

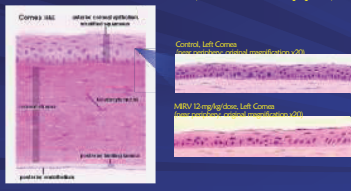
118

Microscopic Analysis of the Corneal Epithelium

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

Key Observations With MIRV 12-mg/kg Dose

- Fewer and larger epithelial cells
- Overall thicker epithelial layer
- Basal layer appearing disorganized as gaps noted between wide 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* 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	Visual Acuity	Slit Lamp Exam
Inquire about ocular symptoms (eg, vision impairments, dry eye, photophobia, eye pain), and treat as appropriate	Measure best corrected visual acuity at baseline to help understand whether changes have occurred during follow-up exams	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 indicated¹

Symptom Assessment ¹	Visual Acuity ¹	Slit Lamp Exam ¹
Inquire about any new or worsening ocular symptoms since the most recent ophthalmic exam	Compare against baseline measurement to determine whether best corrected visual acuity has changed	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 exams¹
- MECs can appear in both symptomatic and asymptomatic patients²
- Document whether MECs are²:
 - Confluent (ie, merging or clumped)
 - Nonconfluent (ie, separated or distinct)

Figure: Anterior dilated corneal microcyst-like changes observed in a 67-year-old patient 8 weeks after receiving ELAHERE™¹

Reprinted by permission from Springer Nature from: Ocular Adverse Events Associated With the Chemotherapy Agent Irinotecan. Springer Nature, 2018. Springer Nature, GmbH, Germany, part of Springer Nature.

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What to Expect With Ocular Events Associated With ELAHERE™

Integrated Safety Analysis of Patients Treated With ELAHERE (N=464)¹

Timing of Onset	Impact	Resolution
Median onset to the first ocular adverse event was ~5 weeks (range, 1 day-55.3 weeks) ¹	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 ²	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*
	Corneal ulcer or stromal opacity or best corrected distance visual acuity of 20/200 or worse	Notify treating oncologist*
Uveitis	Corneal perforation	Monitor
	Grade 1/irre cell in anterior chamber	Monitor
	Grade 2/1+ cell or flare in anterior chamber	Notify treating oncologist*
	Grade 3/+ cell or flare in anterior chamber	Notify treating oncologist*
	Grade 4/hypopyon	Notify treating oncologist*

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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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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