



**Corporate Presentation** 

**JULY 2024** 

Nasdaq: OKYO

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## **Pipeline Focus: OK-101 to Treat Ocular Diseases**





## **OK-101: A Lipid-Conjugated Chemerin Peptide**

Drug candidate with anti-inflammatory and ocular pain reducing properties

Lipid conjugated peptide chemistry minimizes drug washout and enhances the potency

Preservative free, EDTA free

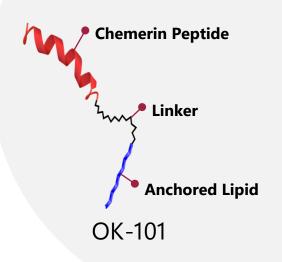
Simple, stable formulation

IND cleared by FDA	December 2022
240 patient trial initiated	May 2023
Top Line data released	Jan 8, 2024

#### **Chemerin Receptor**

#### **Modulates**

Inflammation pain



#### **Receptor localization**

Monocytes, macrophage, dendritic cells, NK cells, Treg cells, spinal cord neurons

#### **Endogenous ligand**

Chemerin: 136 aa peptide





### What is Dry Eye Disease?

Dry eye is a **multifactorial** disease of the ocular surface characterized by a loss of homeostasis of the **tear film**, and accompanied by **ocular symptoms**, in which **tear film instability** and **hyperosmolarity**, ocular surface **inflammation** and **damage**, and **neurosensory abnormalities** play etiological roles.\*

Tear Film Instability Is At Heart Of The Disease

## **Risk & Growth Factors**

Age 50 or older, Female, Wear contact lenses, Digital screen time, Environmental factors

**1,200,000** Treated for DED\*\*

\* Craig JP et al. Ocul Surf. 2017; 15:276; \*\*Market Scope 2023 Dry Eye Product Market Review; does not include OTC artificial tears and other Rx anti-inflammatory and tear stimulants



## **US Regulatory Requirements for Dry Eye Disease\***

#### **Dry Eye: Developing Drugs for Treatment Guidance for Industry**

#### Requirements

- Sign and Symptoms (co-primaries, p<0.05, no unit difference required) can be achieved in separate studies if necessary
- Sign Only (e.g., Schirmer's Responder Rate ≥10 mm, clearing of corneal staining)

Symptom Only (not allowed)

#### Acceptable Signs and Symptoms of Dry Eye

- Signs: corneal staining, conjunctival staining, TFBUT, Schirmer's
- Symptoms: Eye dryness score,
  burning/stinging (ocular irritation), blurred
  vision, light sensitivity, sandy or gritty feeling,
  ocular pain or discomfort



What patients really care about!

\*Source: www.fda.gov/media/144594



#### **Current Standard of Care for DED**

#### FDA-Approved Drugs, Issues Include Slow Onset of Action, Numerous Side Effects & High Discontinuation Rate

Drug Name	Company (Year approved)	Labelled indication	Onset of Action	Primary Sign Endpoint	Primary Symptom Endpoint	Most common Adverse Effects
Restasis; Cyclosporine 0.05%	Allergan (2003)	Sign; BID	up to 6 months	Tear production	N/A	Ocular burning (17%)
Xiidra Lifitegrast 5%	Bausch & Lomb (2016)	Signs and symptoms BID	6-12 weeks	Inferior Corneal Staining Score (ICCS)	Eye dryness score (EDS)	Burning (15%), instillation site reaction (13.2%), dysgeusia (16%) and reduced visual acuity (11.4%).
Cequa Cyclosporine 0.09%	Sun Pharma (2018)	Sign; BID	2 weeks	Tear production	N/A	Pain on instillation of drops (22%) and conjunctival hyperemia (6%).
Eysuvis loteprednol 0.25%	Alcon (2020)	Signs and symptoms QID	4 days	Conjunctival hyperaemia	Ocular discomfort	Instillation site pain (5%)
Tyrvaya; Varenicline 0.3mg	Oyster Point/Viatris (2021)	Signs and symptoms BID	1-4 weeks	Tear production	Eye dryness score (EDS)	Sneezing (82%), cough (16%), throat irritation (13%), and instillation-site (nose) irritation (8%).
Meibo; Perfluorohexyloctane	Bausch & Lomb (2023)	Signs and symptoms QID	2 weeks	Total corneal fluorescein staining	Eye dryness score (EDS)	Blurred vision and conjunctival redness (1-3%)
Vevye; Cyclosporine 0.1%.	Novaliq/Harrow (2023)	Signs and symptoms BID	2 weeks	Tear production	N/A	Instillation site reactions (8%) and temporary decreases in visual acuity (3%).



### **DED Remains Unmet Need Despite Available Therapies**



of 2022 prescriptions for DED were Xiidra and Restasis\*



of these prescriptions are new prescriptions, not refills\*



of patients on Restasis discontinue treatment within 3 months\*\*

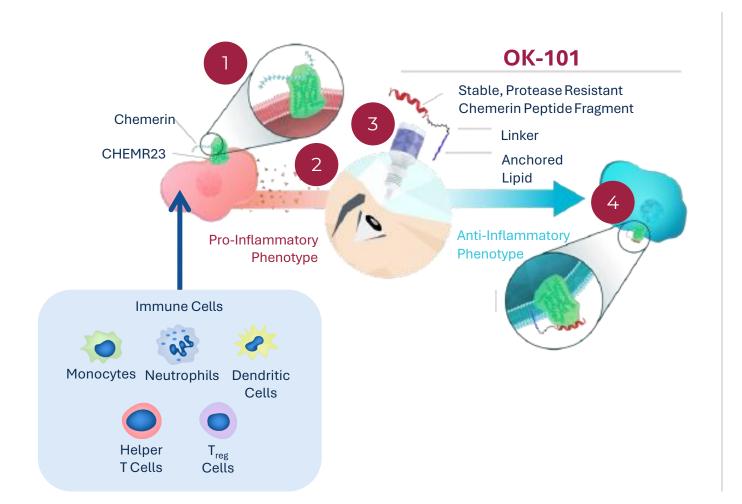


of patients on Xiidra discontinue treatment within the first month\*\*

\*Bloomberg (U.S. Symphony data), August 2023. Note: Does not include generic cyclosporine sales data; \*\*White et al. Clin Ophthalmol. 2019, 13:2285



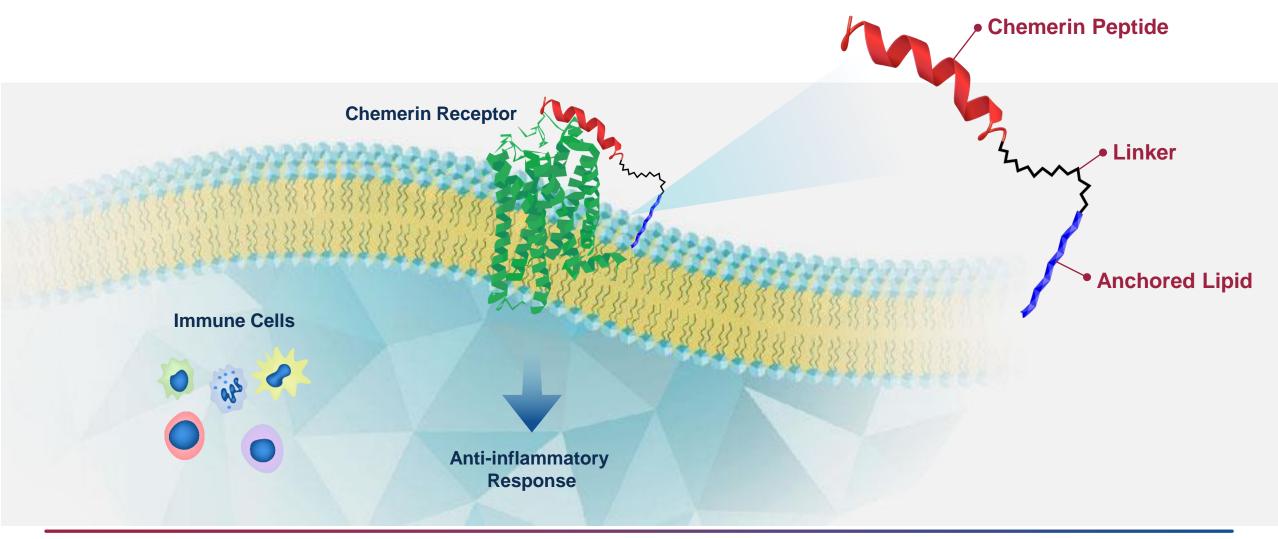
#### **Chemerin Derived Peptide: A Potential Regulator of Inflammation & Pain**



- Pro-inflammatory chemerin activates immune cells at the inflammation site
- Peptides derived from chemerin physiologically inhibit the inflammatory response
- The data suggests that topically administered OK-101 peptide can dramatically enhance the anti-inflammatory response
- Proprietary MAP technology
  designed to enhance residence time
  of OK-101 on ocular surface



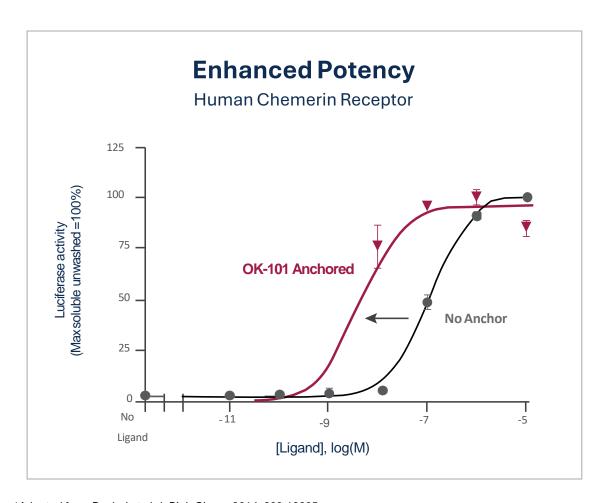
## **OK-101: Targeting Chemerin Receptor**

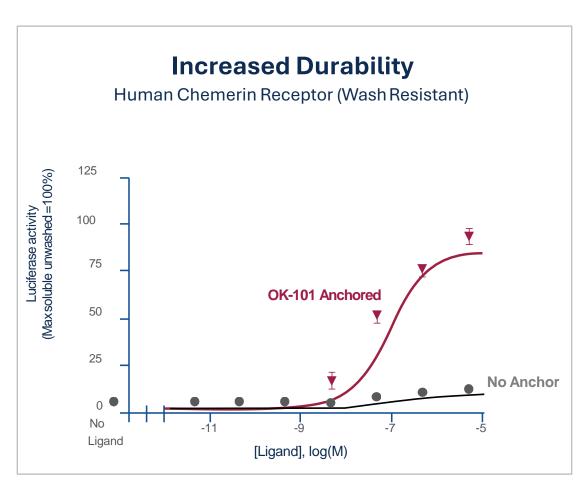




## Membrane Anchoring Improves Potency, Durability

#### \*In-vitro studies

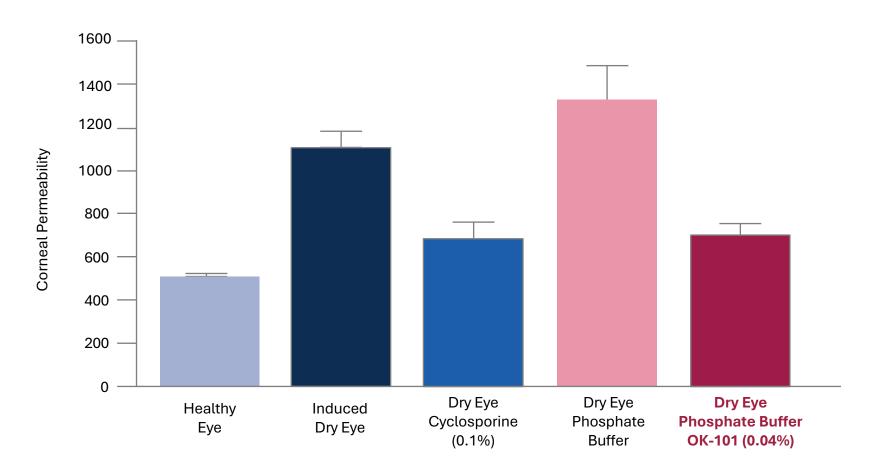


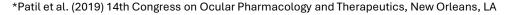


\*Adapted from Doyle J et al, J. Biol. Chem. 2014; 289:13385



## Validation: OK-101 Efficacy in Dry Eye Mouse Model









OK-101 and cyclosporine were administered topically twice a day

Corneal permeability significantly reduced with OK-101 vs phosphate buffer alone

Potency of OK-101 was comparable to cyclosporine, an active ingredient of Restasis (Allergan) & Cequa (Sun Pharma)

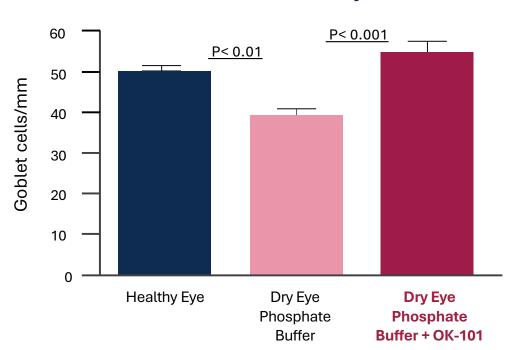
Reducing corneal permeability with OK-101 improves corneal integrity in dry eye mouse model

#### **OK-101 Normalized Goblet Cells & Reduced Inflammatory CD4 T Cells**

#### Increased Mucin-secreting Goblet Cells\*

OK-101: (0.04%) normalized goblet cell density (OK-101 was administered topically twice a day)

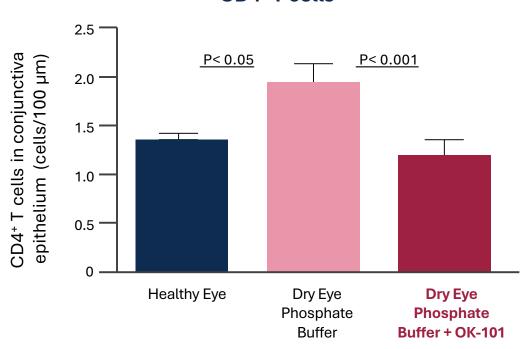
#### **Goblet celldensity**



#### Reduced Inflammatory Biomarkers\*

OK-101: (0.04%) reduced count of CD4+ T cells, which are known biomarkers of inflammation

CD4+ T cells



\*Patil et al. (2019) 14th Congress on Ocular Pharmacology and Therapeutics, New Orleans, LA



## Neuropathic Corneal Pain (NCP) in Dry Eye Disease

DED patients suffer from neuropathic corneal pain, making their condition more resistant to anti-inflammatory drugs

No Current FDA approved topical treatment for neuropathic corneal pain

ChemR23 receptor on leukocytes targeted by OK-101 is **also** expressed on neurons and glial cells in the dorsal root ganglion and spinal cord

DED patients would benefit from a drug that comprises antiinflammatory and neuropathic pain reducing characteristics

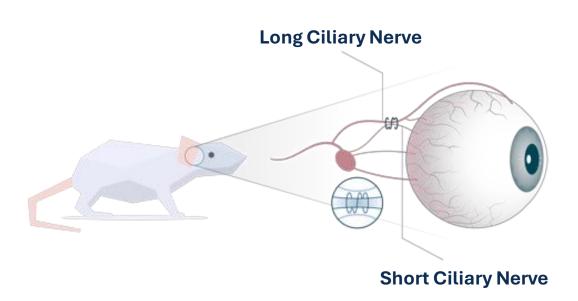
OK-101: a potentially promising candidate for the treatment of both inflammation and pain



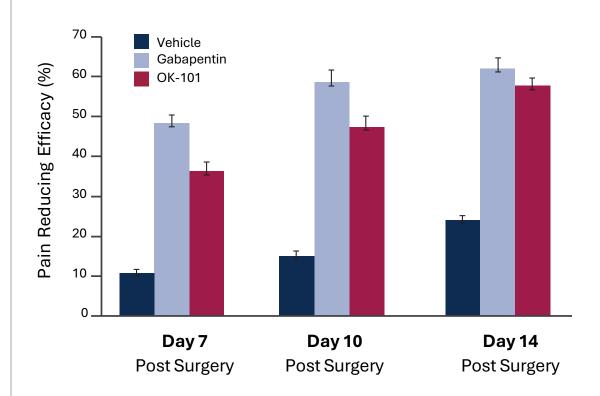


## OK-101 Reduced Neuropathic Corneal Pain ("NCP") in Mouse Model\*

Ciliary Ligation Model\* Illustrates OK-101 Potential to Reduce Ocular Pain. Ciliary nerve ligation surgery to create the corneal neuropathic pain (CNP) model



## OK-101\*\* Reduced Corneal Pain Response Comparable to Gabapentin\*\*\* (GBP)



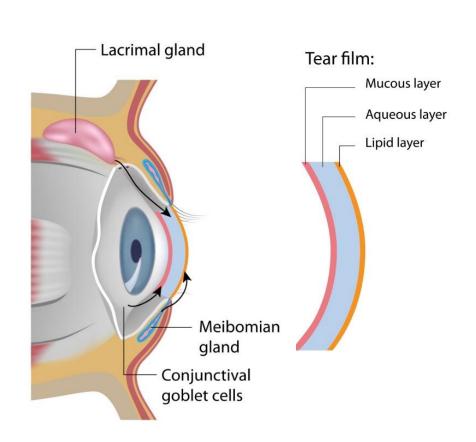
<sup>\*</sup> Collaboration with Dr. Pedram Hamrah, Tufts Medical Center, Boston (Kenyon B, ARVO Abstract 4085, 2020)

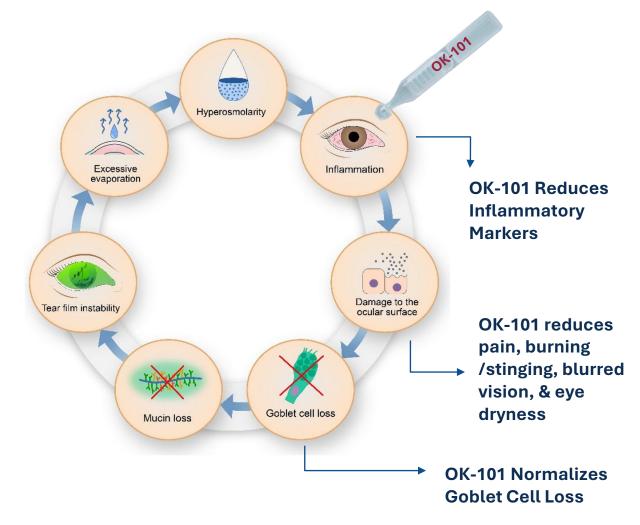
<sup>\*\*\*</sup> Administered by intraperitoneal injection,100 mg/kg once at Day 4, 7, 10, and 14



<sup>\*\*</sup> Topical administration (0.04%)

# OK-101 Believed to Disrupt Dry Eye Cycle by Targeting Inflammation, Improving Tear Film Stability and by Ameliorating Multiple Symptoms





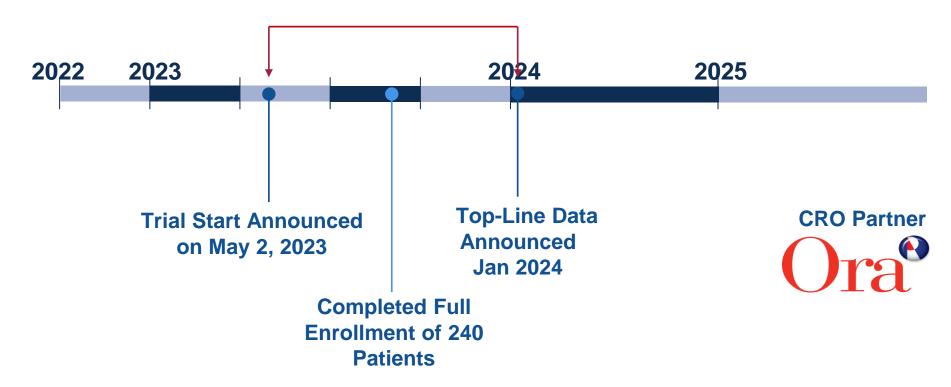
Dry Eye Cycle adapted from: Fineide et al Scientific Reports (2022) 12:21416



### **OK-101 DED Development Timeline**

#### Phase 2

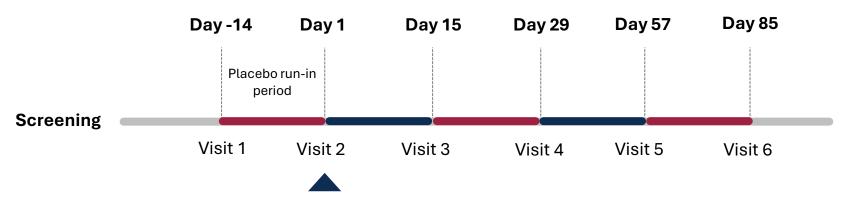
- 240 Subjects; 80 per arm
- 12 Week Dosing
- 6-9 Months Duration
- Potential Registration Trial





### **OK-101 DED Phase 2 Trial Design**

**Note: First Human Trial of OK-101** 



Randomization into one of three cohorts

OK-101 (0.05%) n = 81

OK-101 (0.1%) n = 80

Placebo n = 79

#### **Study Overview**

Total Subjects: Enrolled = 384 Baseline characteristics were balanced amongst treatment groups

Screen Failures = 144 No drug-related SAEs, most AEs were mild stinging & burning

Randomized Subjects = 240 1 discontinuation for iritis in 0.05% OK-101 group



#### **ENDPOINTS**

#### **Primary Endpoints**

(through Day 85)

Inferior Corneal Staining (Sign)

Ocular Discomfort Score (Symptom)

#### **Secondary Endpoints**

Total Conjunctival Staining (sign)

Tear Film Break-up Time (TFBUT) (sign)

**Blurred Vision** 

**Burning/Stinging** 

Pain

Daily Symptom Diary



## **OK-101 Phase 2 DED Study: Patient Demographics**

Category	OK-101 (0.1%)	OK-101 (0.05%)	Placebo	All Subjects
Age (Years): n	80	81	79	240
Mean (SD)	66.2 (10.6)	63.6 (11.98)	64.4 (13.69)	64.7 (12.15)
Median	67.0	63.0	65.0	65.0
Min, Max	35, 85	20, 87	26, 94	20, 94
Sex				
Male: n (%)	30 (37.5)	20 (24.7)	17 (21.5)	67 (27.9)
Female: n (%)	50 (62.5)	61 (75.3)	62 (78.5)	173 (72.1)
Ethnicity				
Hispanic or Latino: n (%)	6 (7.5)	6 (7.4)	2 (2.5)	14 (5.8)
Not Hispanic or Latino: n (%)	74 (92.5)	75 (92.6)	77 (97.5)	226 (94.2)
Race				
American Indian or Alaska Native: n (%)	1 (1.3)	2 (2.5)	2 (2.5)	5 (2.1)
Asian: n (%)	7 (8.8)	9 (11.1)	6 (7.6)	22 (9.2)
Black or African American: n (%)	19 (23.8)	20 (24.7)	8 (10.1)	47 (19.6)
Native Hawaiian or Other Pacific Islander: n (%)	1 (1.3)	0	0	1 (0.4)
White: n (%)	52 (65.0)	50 (61.7)	63 (79.7)	165 (68.8)



## **Baseline Signs & Symptom of Enrolled Subjects were Balanced**

Sign & Symptom Baseline	OK-101 (0.1%)	OK-101 (0.05%)	Placebo	All Subjects
Inferior Fluorescein Staining (0 to 4: Higher is worse)				
Mean (SD)	1.88 (0.554)	1.9 (0.572)	1.92 (0.574)	1.9 (0.565)
Median	2.0	2.0	2.0	2.0
Min, Max	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0
Ora Calibra® Discomfort Scale (0 to 5: Higher is worse)				
Mean (SD)	2.6 (0.84)	2.6 (0.8)	2.7 (0.95)	2.6 (0.86)
Median	3.0	3.0	3.0	3.0
Min, Max	1, 4	1, 4	1, 4	1, 4
Conjunctival Sum Lissamine Green Staining (0 to 8: Higher is Worse)				
Mean (SD)	3.98 (1.504)	3.98 (1.387)	3.94 (1.344)	3.97 (1.408)
Median	3.75	4.0	4.0	4.0
Min, Max	1.5, 8.0	2.0, 8.0	2.0, 8.0	2.0, 8.0
Burning/Stinging from Visual Analog Scale (0 to 100: Higher is Worse)				
Mean (SD)	47.0 (31.12)	54.6 (30.28)	41.1 (32.31)	47.6 (31.59)
Median	50.0	62.0	33.0	50.5
Min, Max	0, 97	0,99	0, 100	0, 100
Pain from Visual Analog Scale (0 to 100: Higher is Worse)				
Mean (SD)	46.4 (31.71)	46.4 (31.71)	38.6 (33.60)	40.3 (32.48)
Median	29.5	50.0	31.0	39.0
Min, Max	0, 99	0,99	0, 99	0, 99
Blurred Vision from Visual Analog Scale (0 to 100: Higher is Worse)				
Mean (SD)	49.7 (30.04)	48.4 (31.12)	38.8 (31.81)	45.7 (31.25)
Median	55.5	52.0	33.0	47.0
Min, Max	0,98	0, 99	0, 95	0, 99



#### **OK-101 Phase 2 DED Study: Ocular Adverse Events**

Category	OK-101 (0.1%) (N = 80)	OK-101 (0.05%) (N = 81)	Placebo (N = 79)
Number of Ocular AEs	7	19	7
Number of Ocular TEAEs	6	16	6
Number of Ocular SAEs	0	0	0
Number of Ocular TE-SAEs	0	0	0
Number of Subjects Withdrawn Study Drug due to Ocular TEAE: n (%)	0	1 (1.2)	1 (1.3)
Number of Subjects with Ocular TEAEs (Severity)			
Mild: n (%)	5 (6.3)	14 (17.3)	4 (5.1)
Moderate: n (%)	0	1 (1.2)	0
Severe: n (%)	0	0	0
Number of Subjects with Ocular TEAEs by Relationship to Study Drug			
Definitely Related: n (%)	4 (5.0)	8 (9.9)	0
Probably Related: n (%)	0	0	0
Possibly Related: n (%)	0	1 (1.2)	3 (3.8)
Not Related: n (%)	1 (1.3)	6 (7.4)	1 (1.3)

#### **OK-101 Drop Comfort: 2 Minutes Post-Instillation Study Eye**

Drop Comfort	OK-101 0.1% (n=79)	OK-101 0.05% (n=77)	Placebo (n=76)
Mean Score (SD)	2.5 (2.32)	2.3 (2.32)	1.8 (1.73)
Median	2.0	1.0	1.5

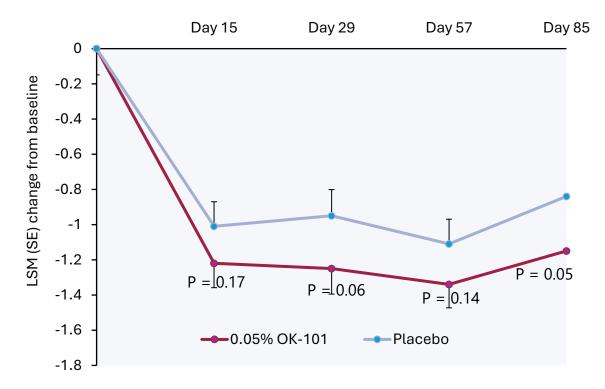
Abbreviations: AE = Adverse Event; TEAE = Treatment-Emergent Adverse Event; SAE = Serious Adverse Event; TE-SAE = Treatment-Emergent Serious Adverse Event.



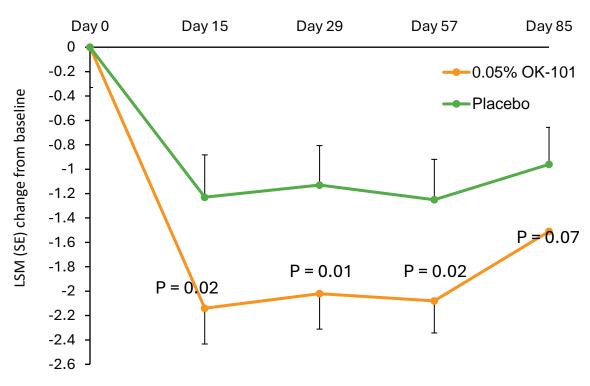
## Improvement in Conjunctival Sum Lissamine Green Staining\* (Sign)

#### Data shown is change from baseline using 0-8 scale in Intent-to-Treat and Above Median Population

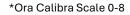
P values are vs placebo based on ANCOVA Model



OK-101 (n = 81), Placebo (n = 79)

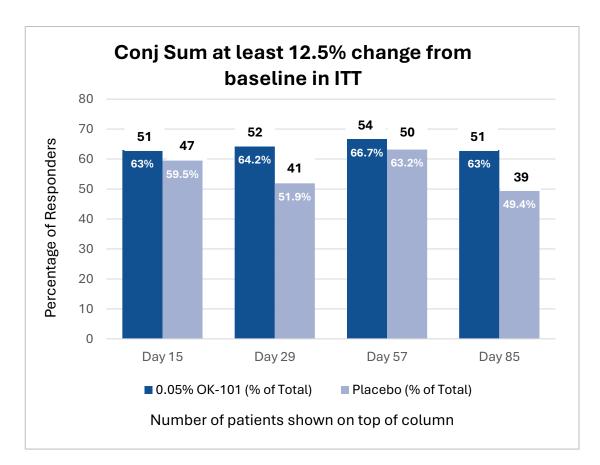


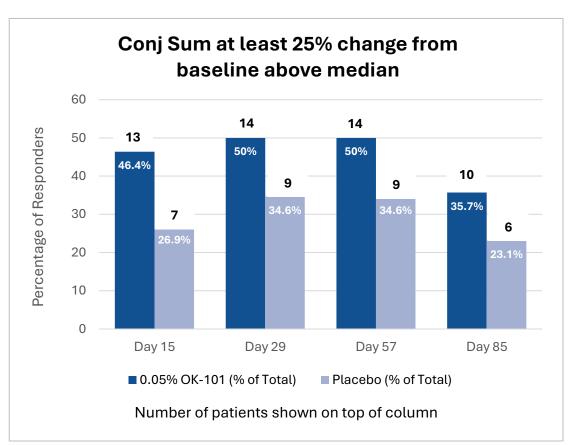
% Change from baseline (5.5)						
Group	Day 15	Day 29	Day 57	Day 85		
OK-101 (n = 26)	38.9	36.7	37.8	27.4		
Placebo (n =28)	22.3	20.5	22.7	17.4		
Change	16.6	16.2	15.1	10		



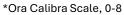


## Percentage of Responders With Improvement in Conjunctival Sum Lissamine Green Staining\*, Intent-to-Treat and Above Median Population





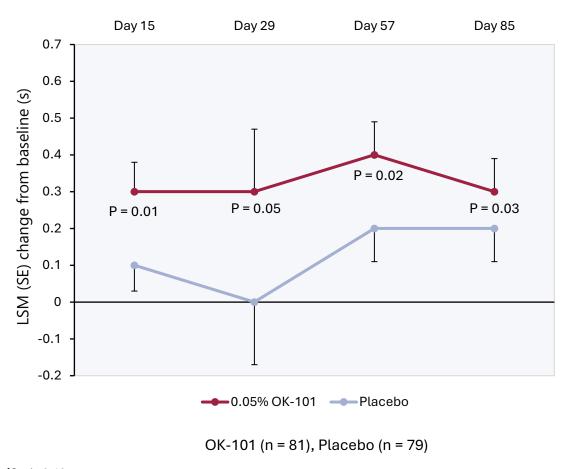
Percentage of OK-101 responders with improvement in Conjunctival Sum staining at each visit was higher than placebo in Intent-to-Treat population as well as the Above Median population



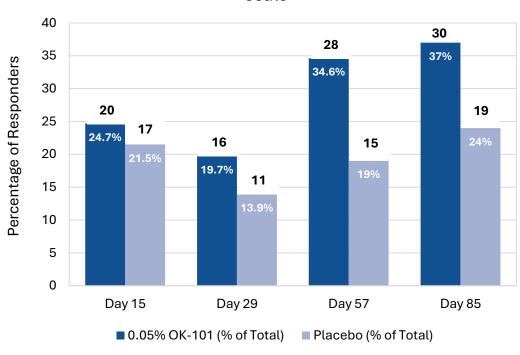


## Significant Improvement in Tear Film Break Up Time<sup>1</sup> (Sign)

Data shown is change from baseline using 0-10 scale in Intent-To-Treat Population P values are vs placebo based on Wilcoxon rank sum test



At least 0.5 sec change from baseline using 0-10 scale



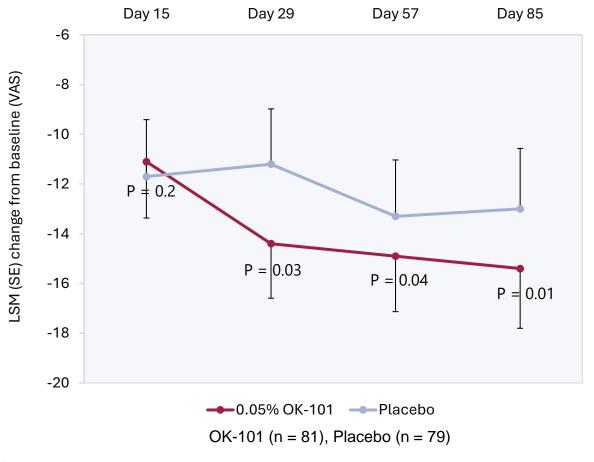
Number of patients is shown on the top of column

<sup>1</sup>Scale 0-10 sec

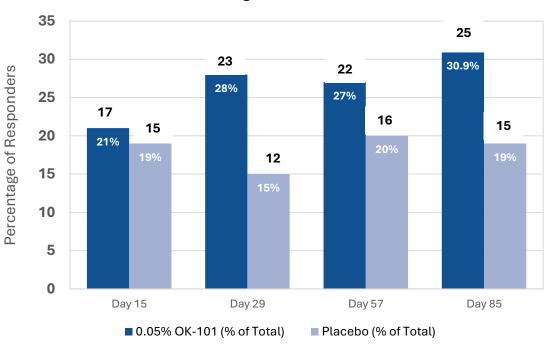


## Significant Improvement in Pain<sup>1</sup> (Symptom)

Data shown is change from baseline using 0-100 Visual Analog Scale in Intent-To-Treat Population P values are vs placebo based on Wilcoxon rank sum test



VAS-Pain at least 30 unit change from baseline using 0-100 Scale



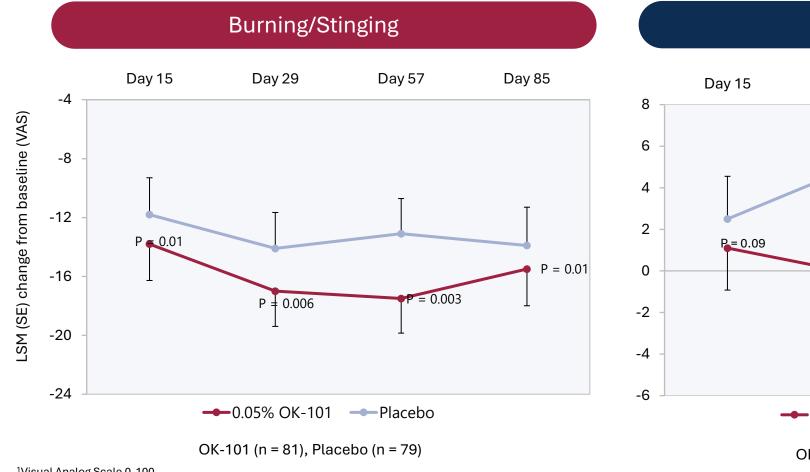
Number of patients shown on top of column

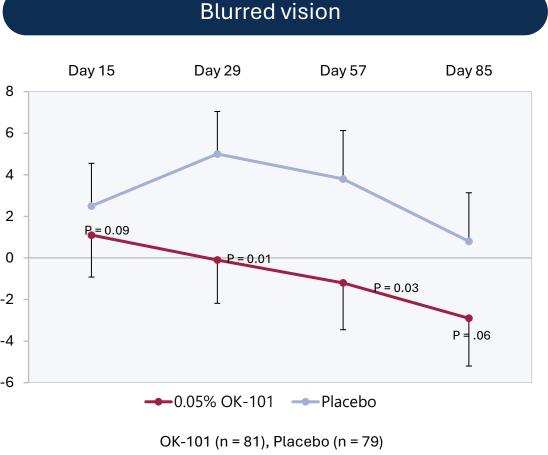
<sup>1</sup>Visual Analog Scale 0-100



## Significant Improvement in Burning/Stinging & Blurred Vision (Symptoms<sup>1</sup>)

Data shown is change from baseline using 0-100 Visual Analog Scale in Intent-To-Treat Population P values are vs placebo based on Wilcoxon rank sum test

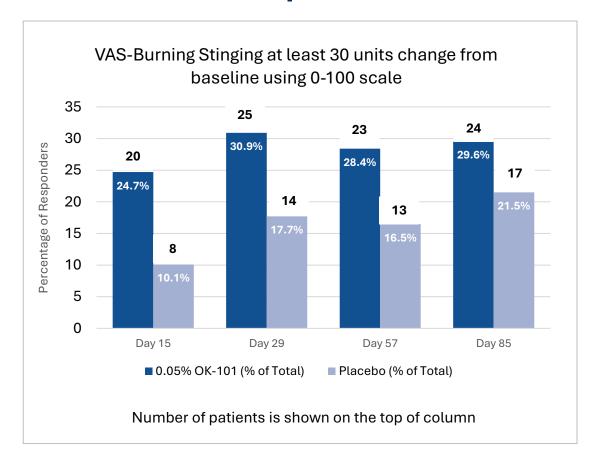


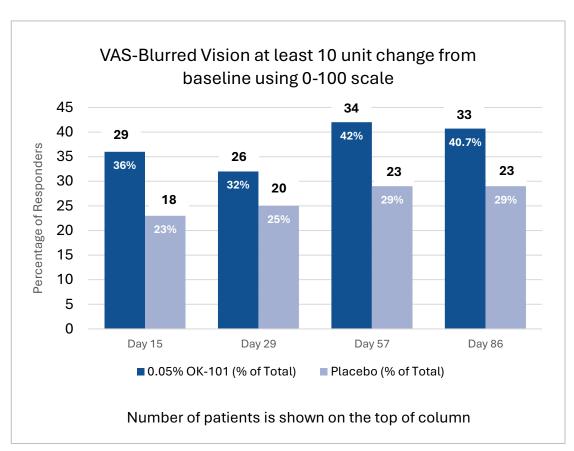






# Responders With Improvement in Burning/Stinging<sup>1</sup> and Blurred Vision<sup>1</sup>, Intent-to-Treat Population



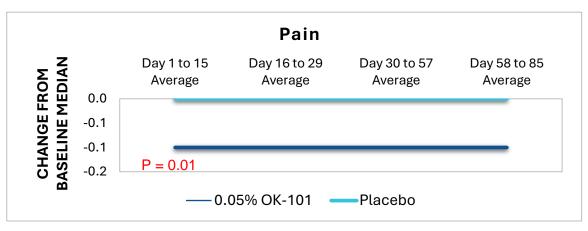


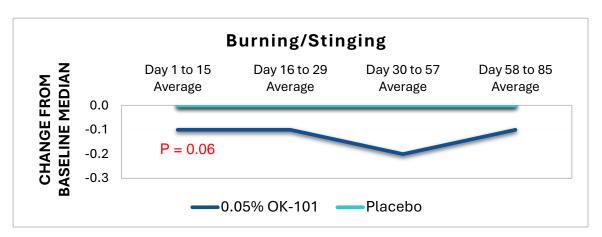
Percentage of OK-101 responders with improvement in burning/stinging and blurred vision at each visit was higher than placebo in Intent-to-Treat population

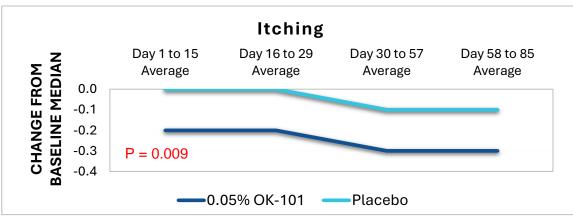
<sup>1</sup>Visual Analog Scale 0-100

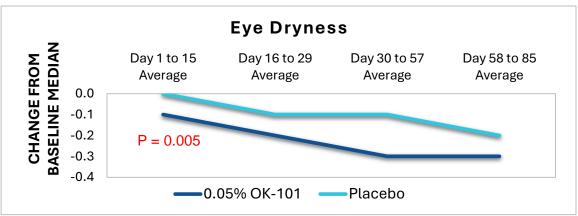


## Significant Improvement in Symptoms by Patient Reported Daily Diary Within First Two Weeks







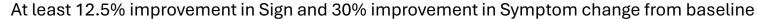


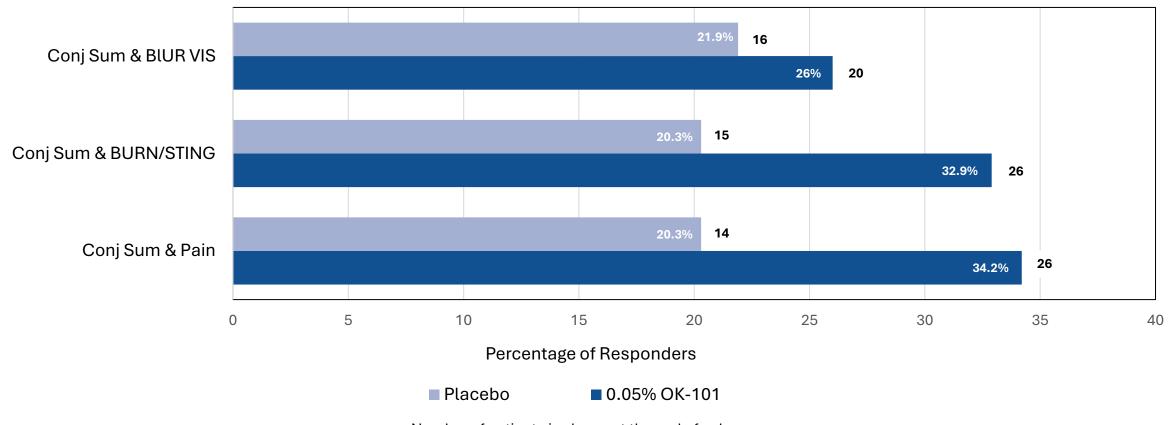
**Diary Symptoms Improvement Sustained Throughout the Trial** 





# Responders With Improvement in Both Signs\*<sup>1</sup> and Symptoms<sup>2</sup> at Day 85 ITT Population





Number of patients is shown at the end of column

 $^{\star}$ Ora Calibra Scale, 0-8 scale,  $^{1}$ Lissamine Green Staining  $^{2}$ Visual Analog Scale (VAS) 0-100;





OK-101 to Treat Neuropathic Corneal Pain (NCP)

#### Plans for OK-101 to Treat Neuropathic Corneal Pain (NCP)

>> Agreement with Tufts Medical Center for NCP Phase 2 Trial Announced on July 2023

NCP Trial to be Conducted by Pedram Hamrah, MD, Professor, at Tufts Medical Center

>> IND Cleared by FDA for OK-101 to Treat NCP Announced on Feb. 9, 2024

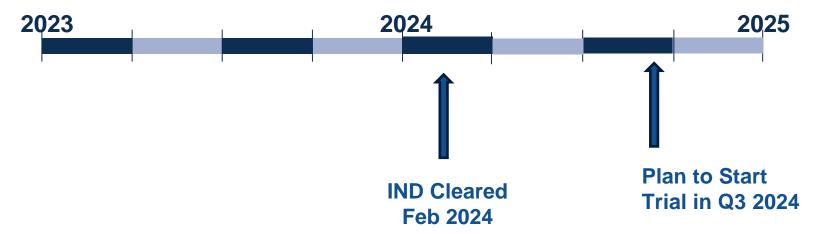
Phase 2 Randomized, Placebo-Controlled Trial Planned to be Initiated in Q3 2024



## Plan to Start Phase 2 Trial for OK-101 to Treat Neuropathic Corneal Pain (NCP)

## Phase 2, Randomized, Double masked, Placebo-Controlled Study Assessing Safety and Efficacy of OK-101 in Subjects with NCP

- 48 subjects to be enrolled
- Three arms, 0.05% OK-101, 0.1% OK-101 and Placebo, (16 per arms)
- Five visits over the course of 16 weeks
- Study duration: 9-12 months
- Pedram Hamrah, MD, Principal Investigator, Tufts Medical Center





#### **Patent Protection Through at Least 2039**

#### **OK-101 Technology:**

Composition of Matter: US 10,233,219

Issued in US to 2034 with potential patent term extension up to 2039

Method of Use (Dry Eye): US 11,197,906

Issued in US to 2037 with potential patent term extension up to 2042

Use (Neuropathic Pain): US 11,254,720

Issued in US to 2034 (+187 days of \*PTA)



## **Experienced Team With Considerable Drug Development Expertise**

#### **Management**

Gary S. Jacob, PhD. Chief Executive Officer and Director Co-inventor and developer of Synergy's FDA-approved drug Trulance, currently marketed by Bausch Health, Inc. 35 years of experience in the pharmaceutical and biotechnology industries.









Raj Patil, PhD, Chief Scientific Officer 30 years of academic/pharmaceutical R&D experience and leadership experience at Alcon, Novartis and Ora, all leaders in Ophthalmology.









Keeren Shah, Chief Financial Officer 20 years of experience in controllership, financial planning and analysis, IPO offering and variety of finance positions at Visa Inc, Arthur Andersen, BBC Worldwide, Tiziana Life Sciences and Accustem Inc.









#### **Board**

Gabriele Cerrone Chairman, Founder Extensive experience founding, financing, restructuring, and listing multiple micro-cap biotechnology companies in oncology, infectious diseases, and molecular diagnostics.









Bernard Denoyer, Non-Executive Director Extensive financial management experience as Senior Vice President of Synergy Pharmaceuticals, Inc. Also served as CFO and Senior Vice President of META Group, Inc.





Gary S. Jacob, PhD, Chief Executive Officer and Director 35 years of experience in the pharmaceutical and biotechnology industries, R&D, operations, business development and capital financing activities.

John Brancaccio, Non-Executive Director Financial executive with international and domestic experience in pharmaceutical and biotechnology companies





Willy Simon, Non-Executive Director International banking experience gained in senior leadership positions at multiple financial institutions.







## **Key Takeaways**



Significant drug effects were observed in multiple signs (<u>conjunctival staining</u>, <u>TFBUT</u>) and symptoms (<u>ocular pain</u>, <u>burning/stinging and blurred vision</u>) of DED as early as the 15-days after dosing.



Drug effect was durable throughout the trial for a number of endpoints.



Significant improvements were observed across multiple <u>symptoms as measured in a daily symptom diary</u> including pain, eye dryness and itching within the first two weeks of treatment.



OK-101 exhibited <u>excellent drop comfort</u>, comparable to that of artificial tear, with a favorable adverse event profile and no drug-related serious adverse events.



These observed endpoints support the proposed mechanism-of-action of <u>restoring goblet cell loss</u> by OK-101 as demonstrated in preclinical animal models.



