



Targeting Dry
Eye Disease with
OK-101



Corporate Presentation

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Nasdaq: OKYO

LSE: OKYO

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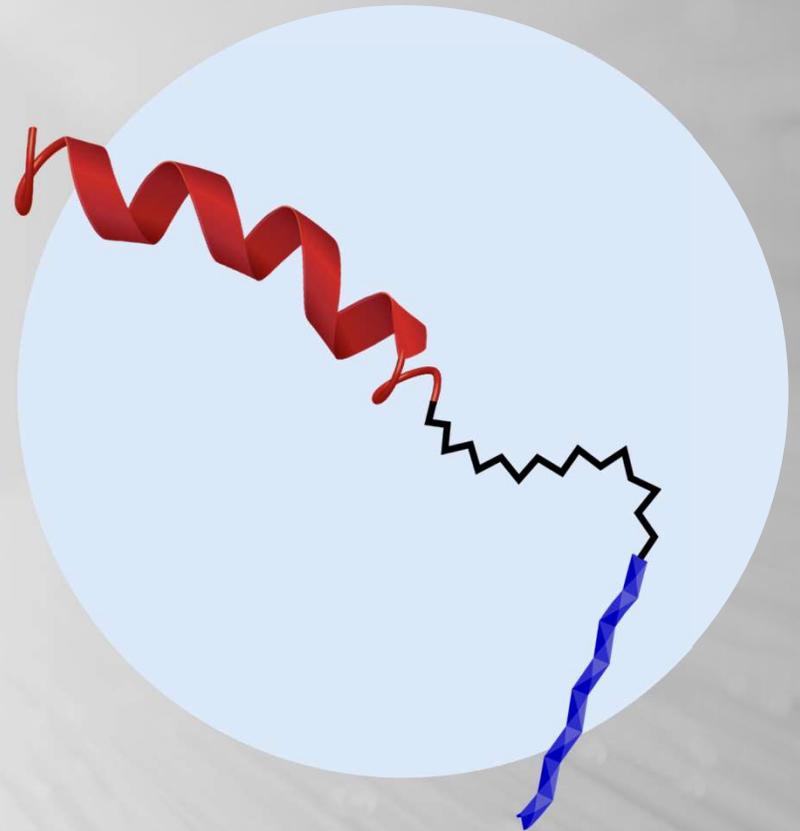
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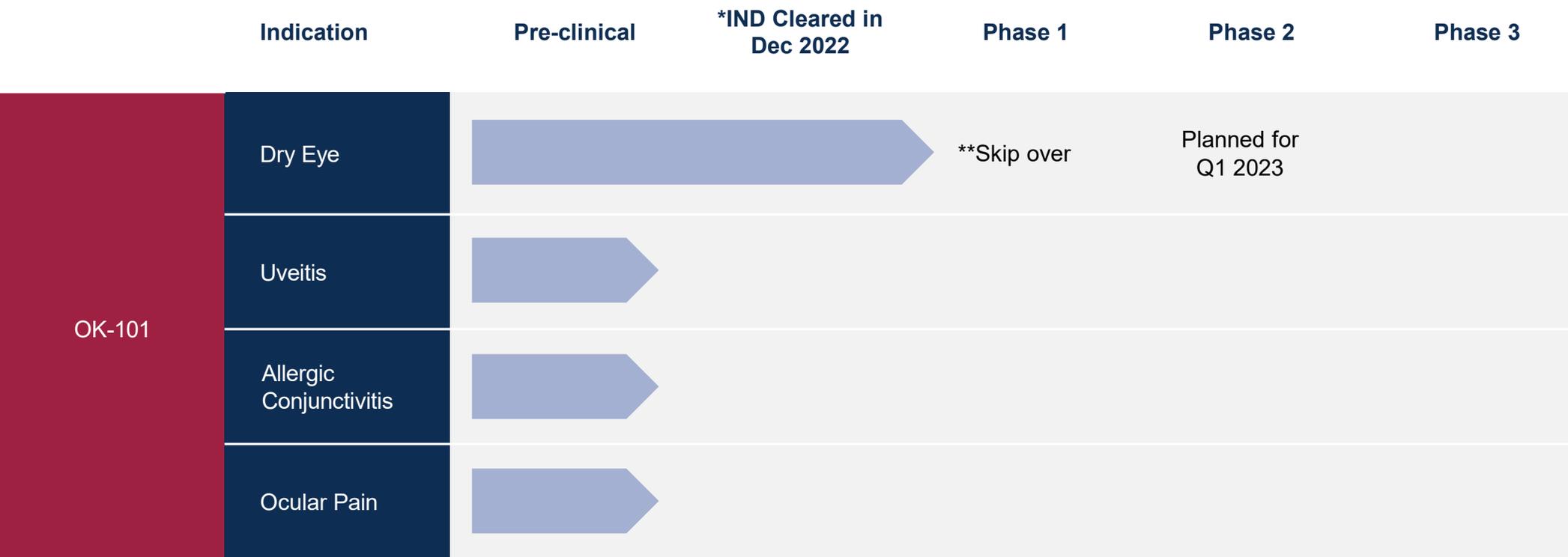
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OK-101

New Chemical Entity Targeting both Inflammation
and Ocular Pain in Dry Eye Disease

Pipeline Focus: OK-101 to Treat Dry Eye Disease



*IND Submitted to FDA on November 18, 2022

**Pre-IND Meeting confirmed FDA concurs with plan to open first trial as Phase 2 in DED patients

Dry Eye Disease: Overview



Ocular Surface Damage

Inadequate or unstable tears resulting in lack of moisture and progressive damage to the ocular surface

Inflammation & Pain: Key Symptoms of Dry Eye

Tear film instability triggers chronic inflammation which leads to symptoms of pain, itchiness, burning, and blurry vision

360,000,000

Worldwide patients

20,000,000

US patients

35%

+50 yrs old affected

Risk & Growth Factors

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



Sources: Papas et al. Ophthalmic Physiol Opt. 2021; 41:1254
Farrand et al. AJO. 2017;182:90; Dana et al, AJO 2019, 202:47
Gayton et al. (2009) Clinical Ophthalmology; 3 405-412

Limits of Current Standard of Care

5 FDA Approved Drugs on Market With Inadequate Efficacy, Slow Onset of Action, and Numerous Side Effects

	API	¹ Limitations
Restasis Allergan	0.05% cyclosporine	Delayed response, up to 6 months to improve symptoms, burning sensation when instilled ² 70% patients do not refill Rx at Month 12
Xiidra Novartis	5% LFA-1antagonist	Eye irritation and burning sensation, change in taste ² 70% patients do not refill Rx at Month 12
Cequa Sun Pharma	0.09% cyclosporine	Burning, pain upon instillation, blurry vision, UTI (side effects on label)
Eysuvis Kala Pharma	0.25% loteprednol	Short-term treatment only (maximum 2 weeks)
Tyrvaya Oyster Point	0.03 mg / inhalation Varenicline	Sneezing, cough & throat irritation (side effects on label)

¹ Side Effect profiles from Drug Labels

² White DE, (2020) Ocular Surgery News: Issue February 25, 2020

Global DED* Market Expected to Reach ~\$6.5 Billion by 2027



\$3.8 Billion Annual Healthcare Costs*



~\$50 Billion Annual Healthcare Costs †



Current Treatment Options Inadequate



More Effective Treatment May Increase Market Size

OK-101: A Lipid-Conjugated Chemerin Peptide

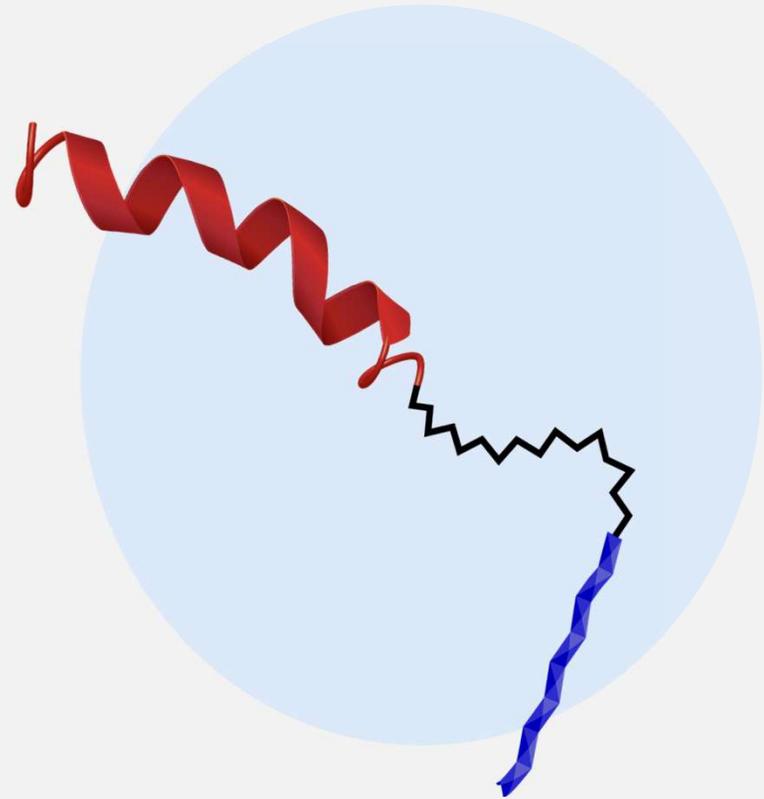
First-in-class drug candidate with anti-inflammatory and ocular pain reducing property

Lipid conjugated peptide chemistry minimizes drug washout and enhances the potency

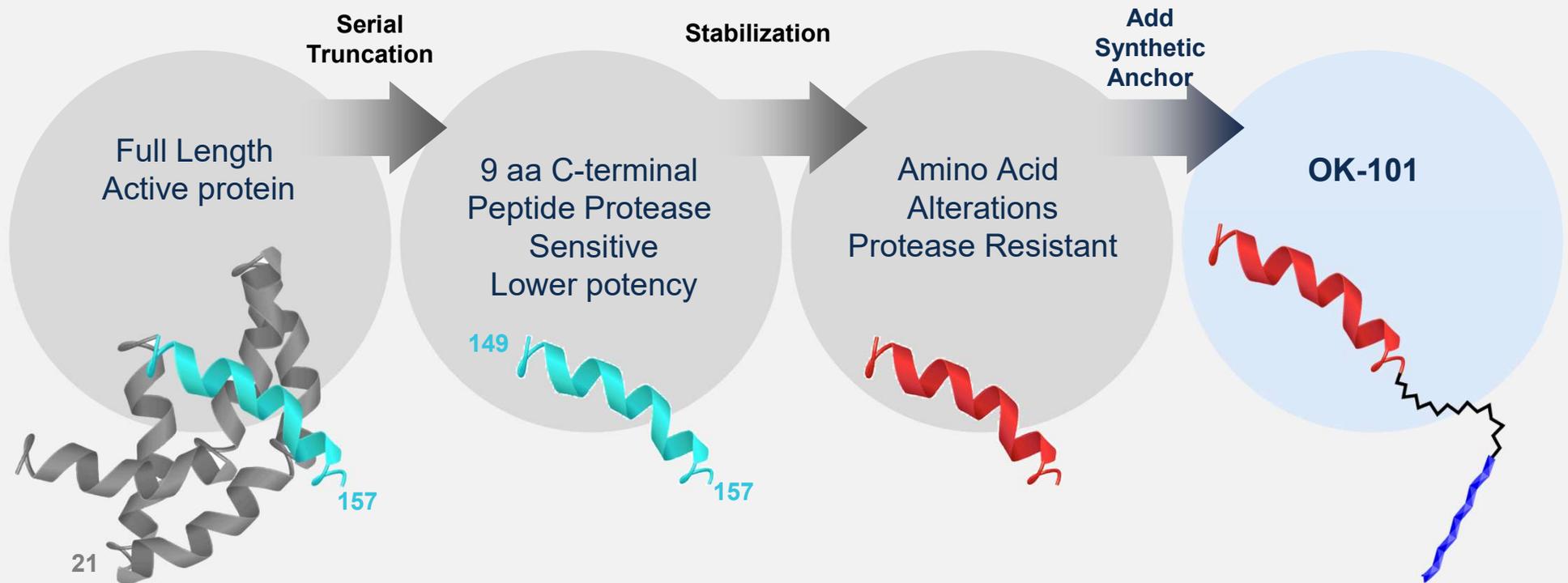
Preservative free, EDTA free

Simple, stable formulation

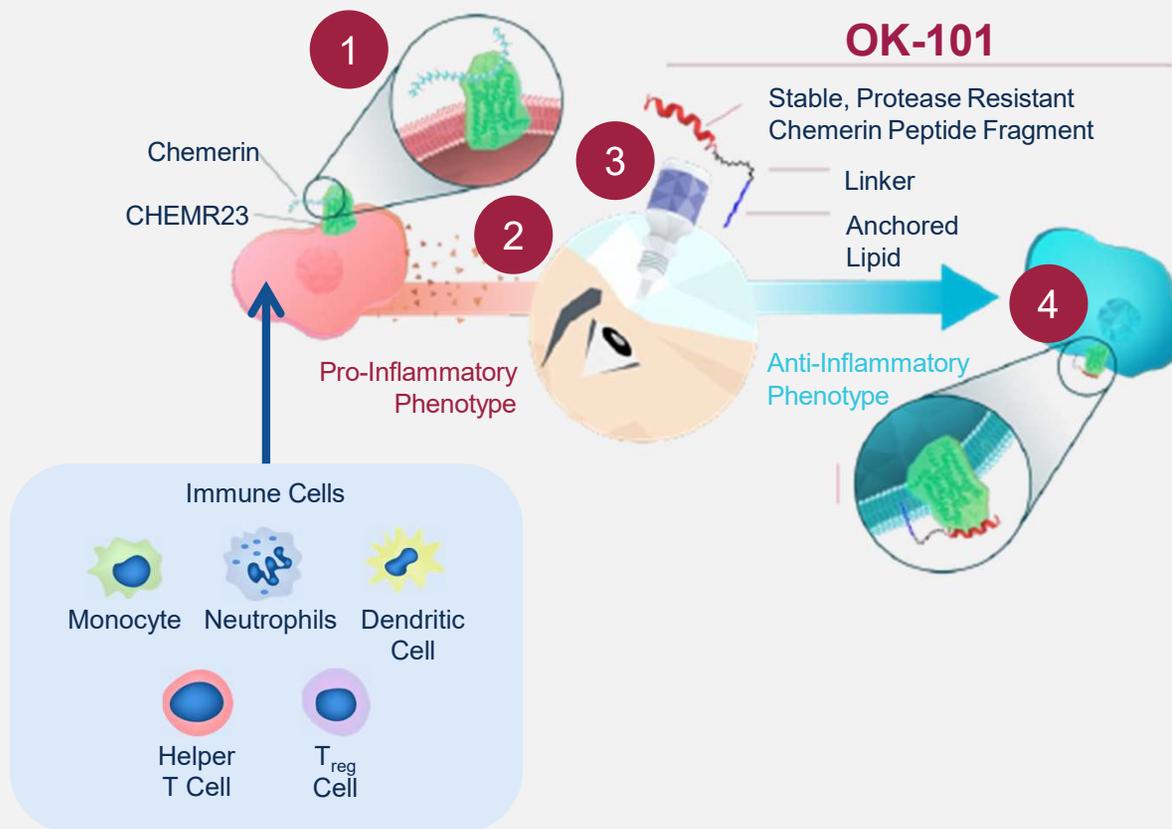
OKYO has exclusive license for OK-101, a novel membrane-anchored chemerin peptide from OTTx Therapeutics (Boston, MA)



Development of OK-101 Using Proprietary MAP* Technology

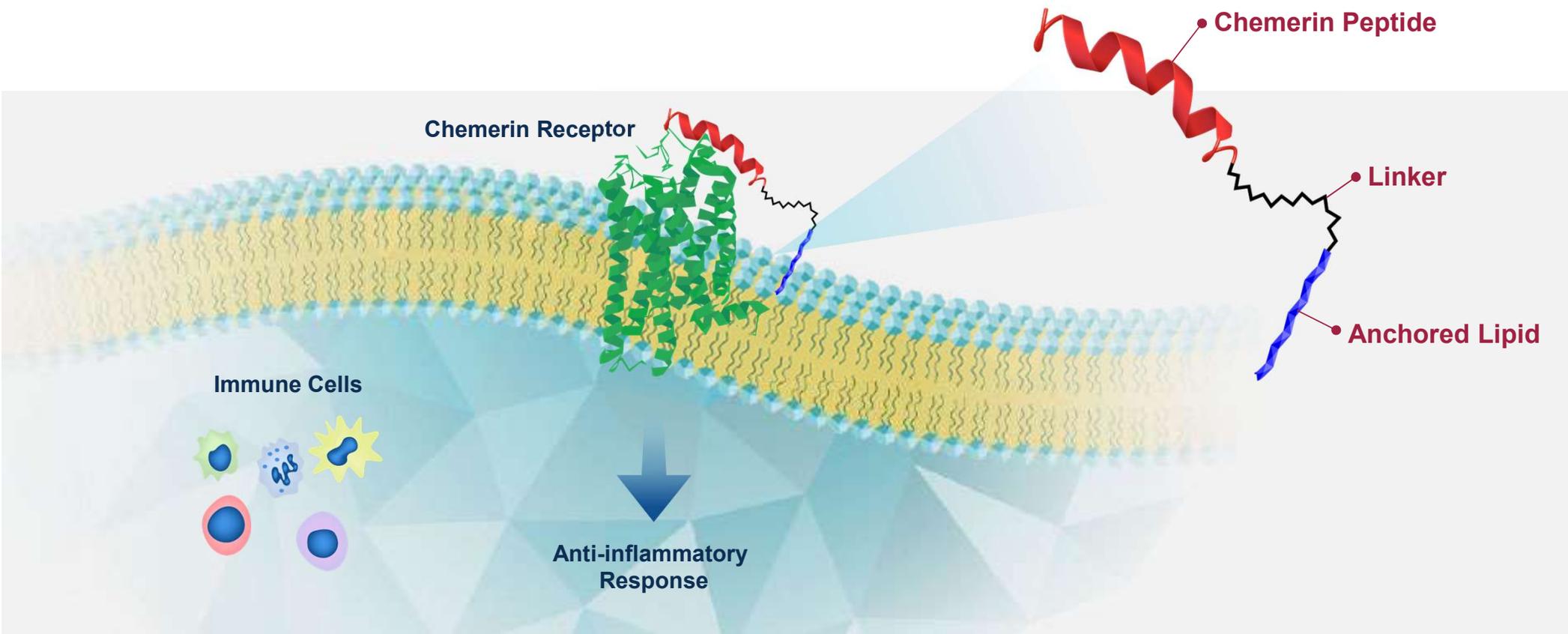


Chemerin Derived Peptide: A Potential Regulator of Inflammation & Pain



- 1. Pro-inflammatory chemerin activates immune cells at the inflammation site**
- 2. Peptides derived from chemerin physiologically inhibit the inflammatory response**
- 3. Topically administered OK-101 peptide can dramatically enhance the anti-inflammatory response**
- 4. Proprietary MAP technology enhances residence time of OK-101 on ocular surface**

OK-101: Targeting Chemerin Receptor

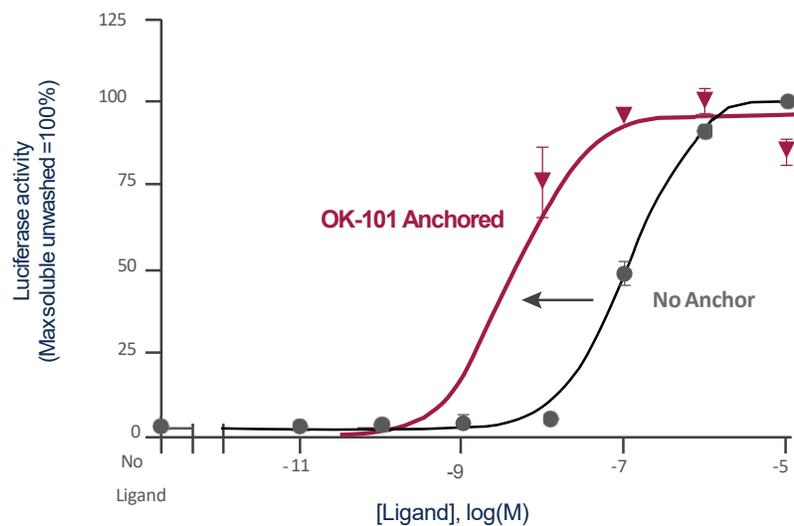


Membrane Anchoring Improves Potency, Durability

*In-vitro studies

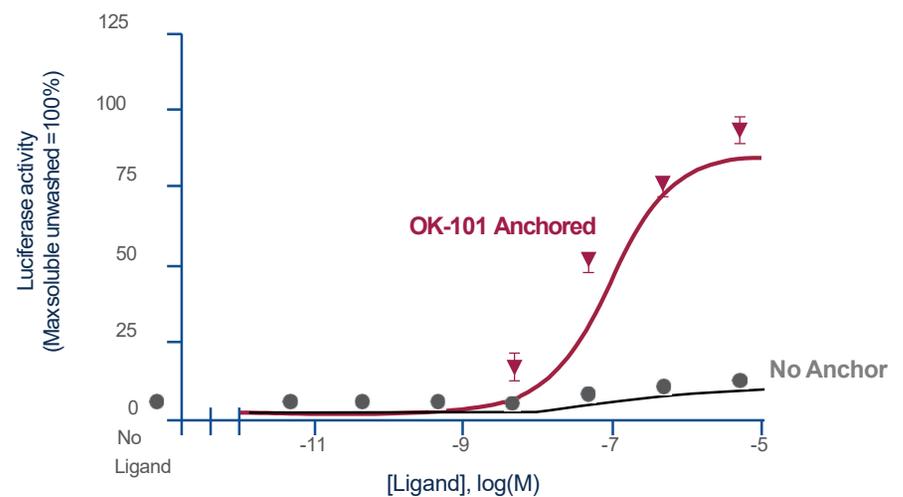
Enhanced Potency

Human Chemerin Receptor

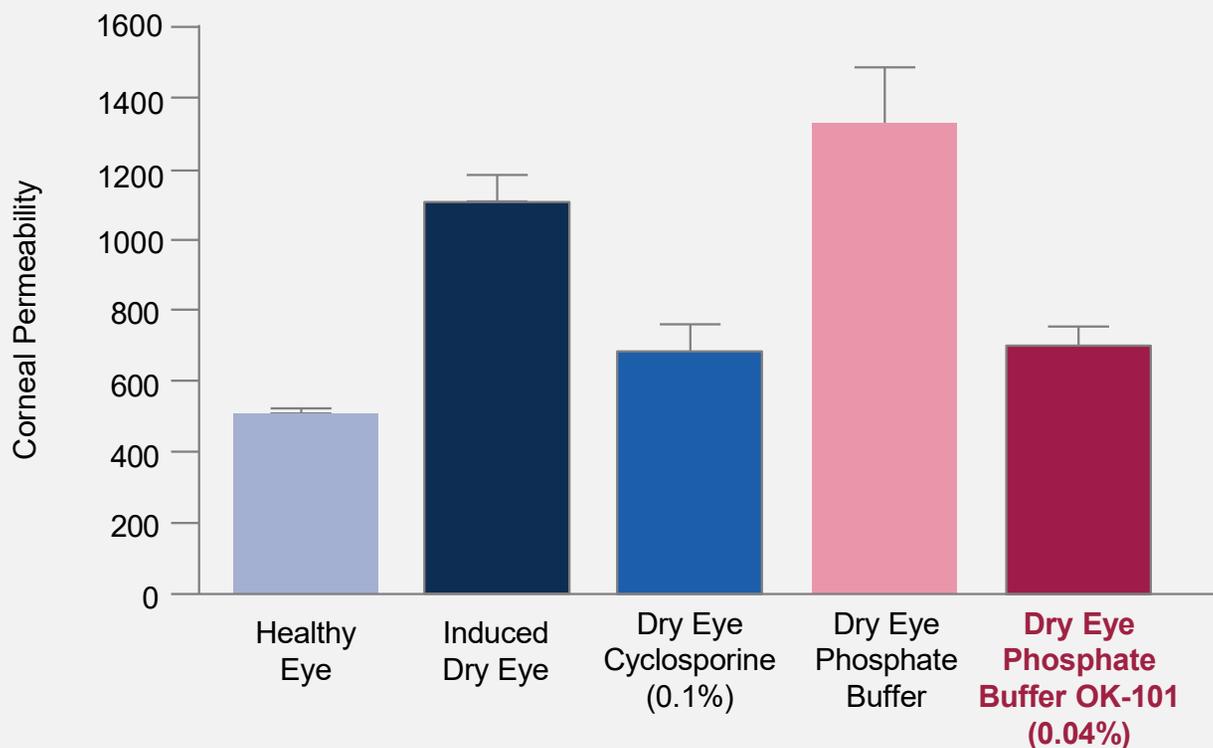


Increased Durability

Human Chemerin Receptor (Wash Resistant)



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)

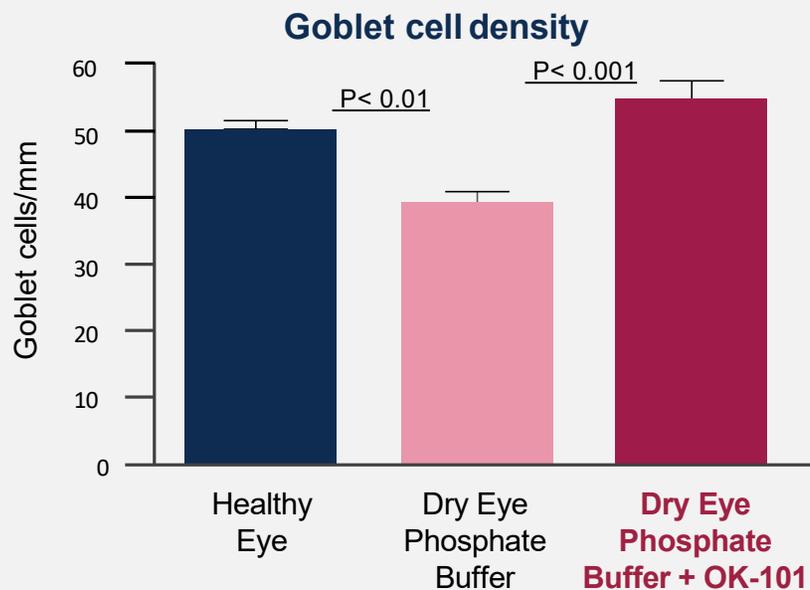
Reducing corneal permeability with OK-101 improves corneal integrity in dry eye mouse model

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

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

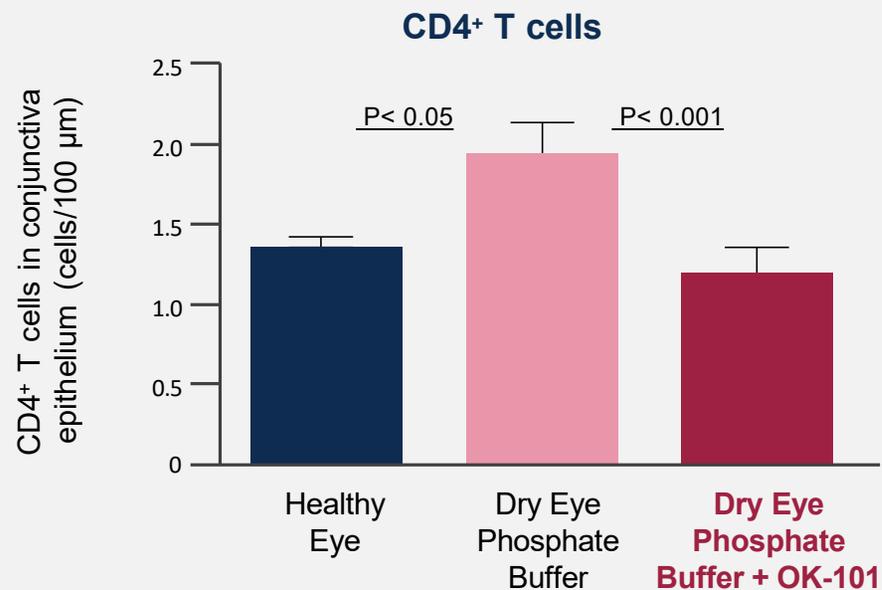
Increased Mucin-secreting Goblet Cells*

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



Reduced Inflammatory Biomarkers*

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



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

Corneal Neuropathic Pain in Dry Eye Disease



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

No FDA approved topical treatment for ocular 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

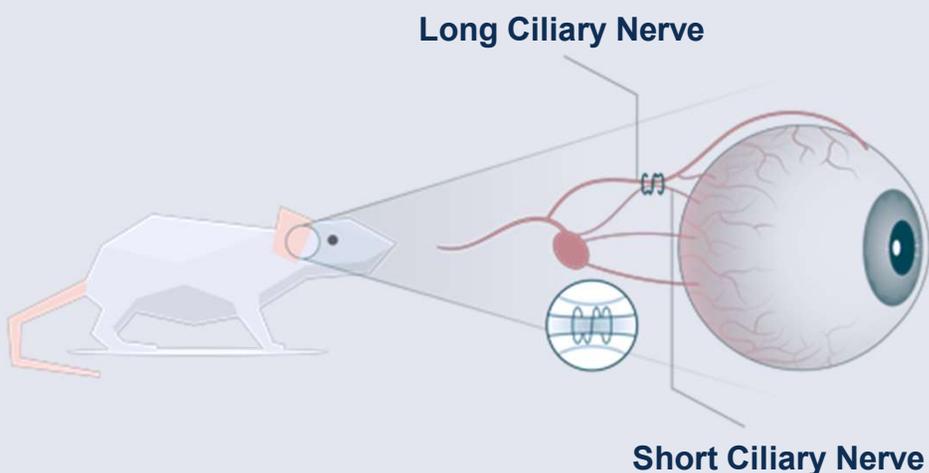
Such patients would benefit from a drug that comprises anti-inflammatory and neuropathic pain reducing characteristics

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

OK-101 Reduced Corneal Neuropathic Pain in Mouse Model

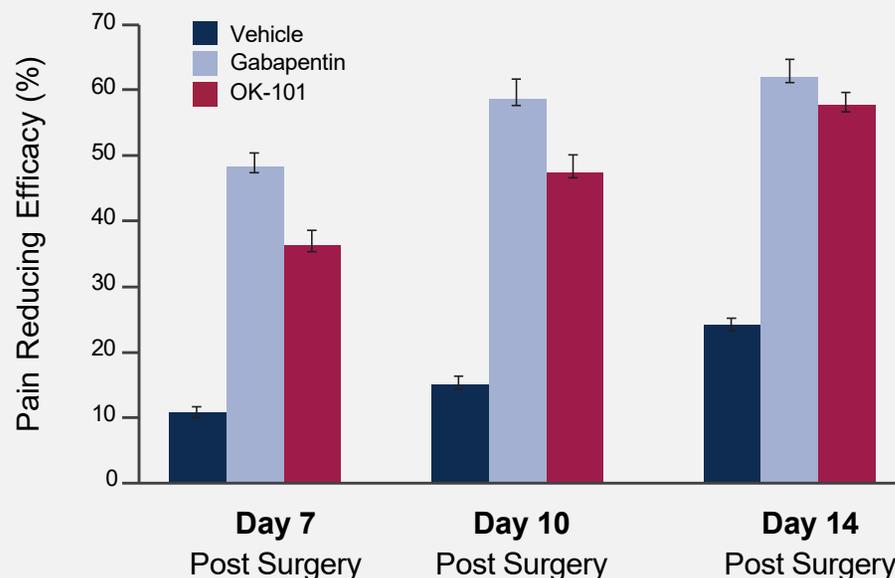
Ciliary Ligation Model* Illustrates OK-101 Potential to Reduce Ocular Pain

Ciliary nerve ligation surgery to create the corneal neuropathic pain (CNP) model



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

OK-101¹ Reduced Corneal Pain Response Similar to Gabapentin² (GBP)



- 1 Topical administration (0.04%)
- 2 Administered by intraperitoneal injection, 100 mg/kg once at Day 4, 7, 10, and 14

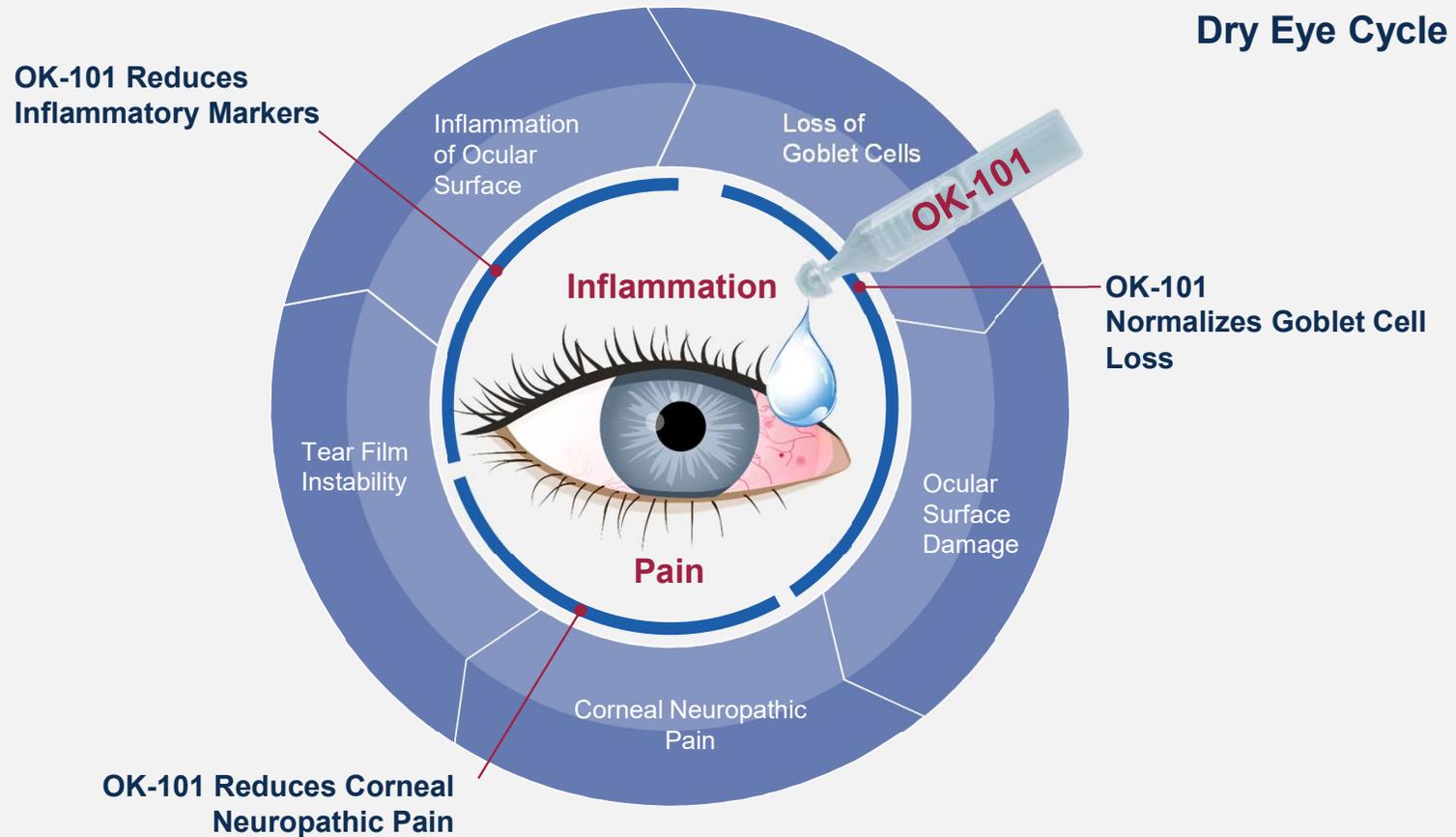
OK-101 Addresses Inflammation and Pain Components of Dry Eye

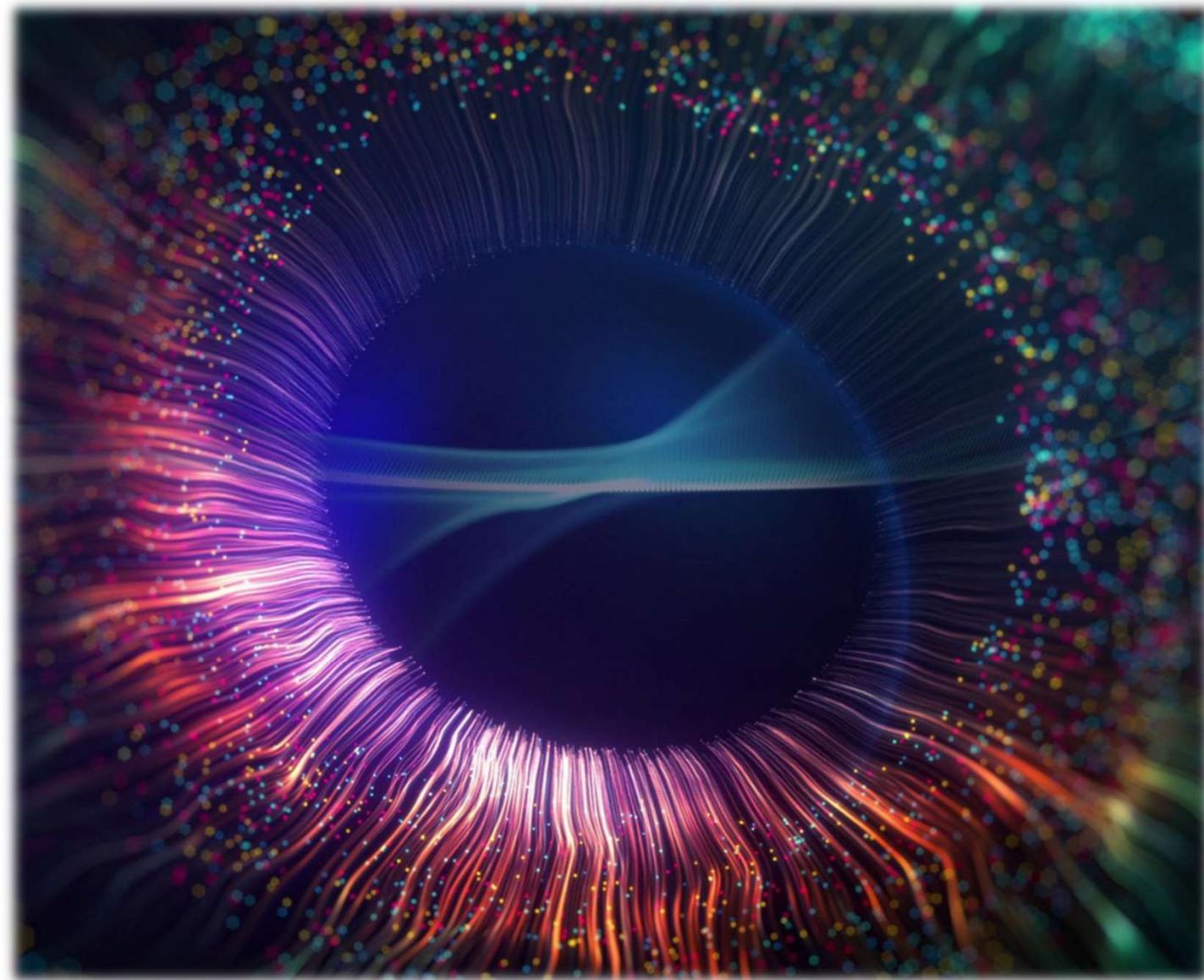
Extrinsic Factors:

- Contact lens
- Digital screen time
- Allergies
- Surgery
- Blepharitis C

Intrinsic Factors:

- Aging
- Sex steroid imbalance
- Autoimmune diseases



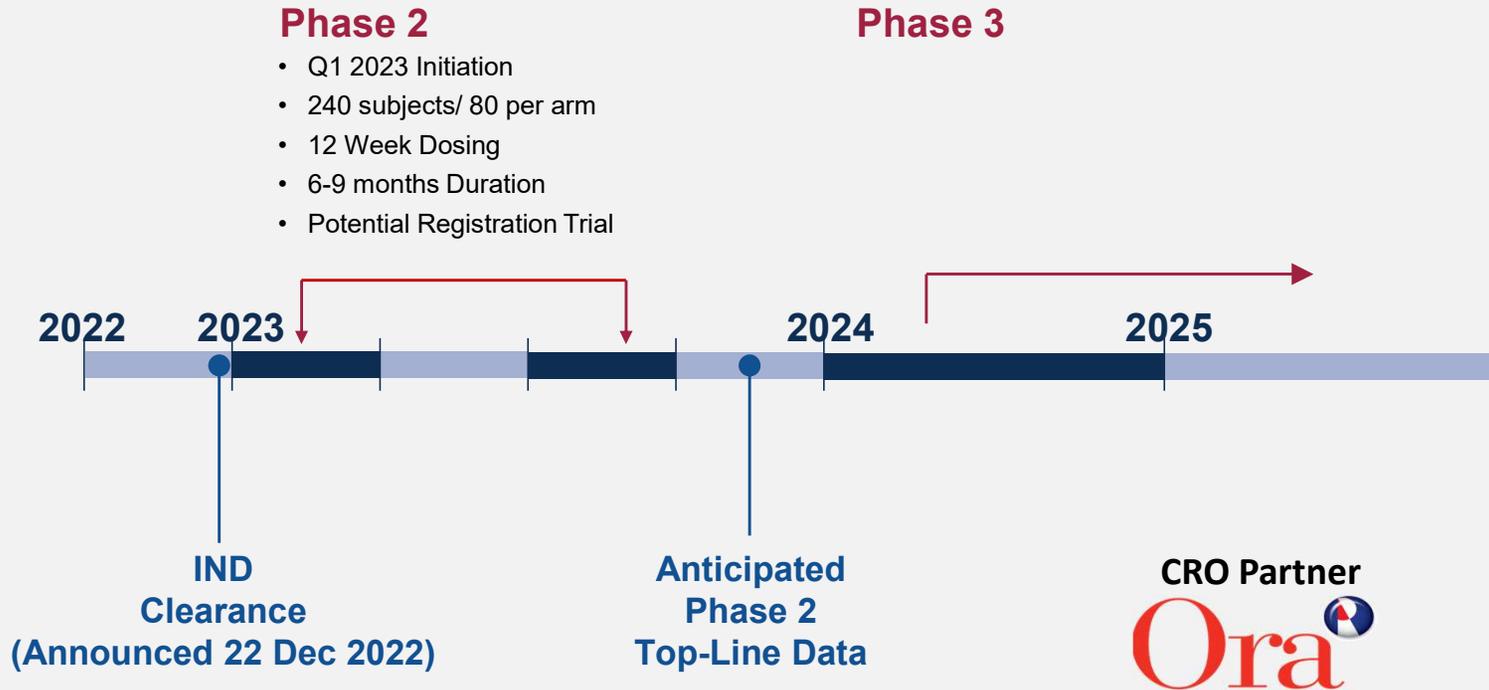


OK-101
Clinical Development

Successful Pre-IND Meeting with FDA OK-101 IND Clearance for DED Announced on 22 December 2022

- >> Pre-IND Meeting Held February 2022
- >> FDA Concur First In-human Trial to be Phase 2
- >> FDA Agrees on Pre-Specified Co-primary Endpoints (Signs and Symptoms) in Planned Phase 2 Trial
- >> OK-101 IND Clearance announced December 22, 2022

OK-101 Development Timeline



Phase 2 Trial Design

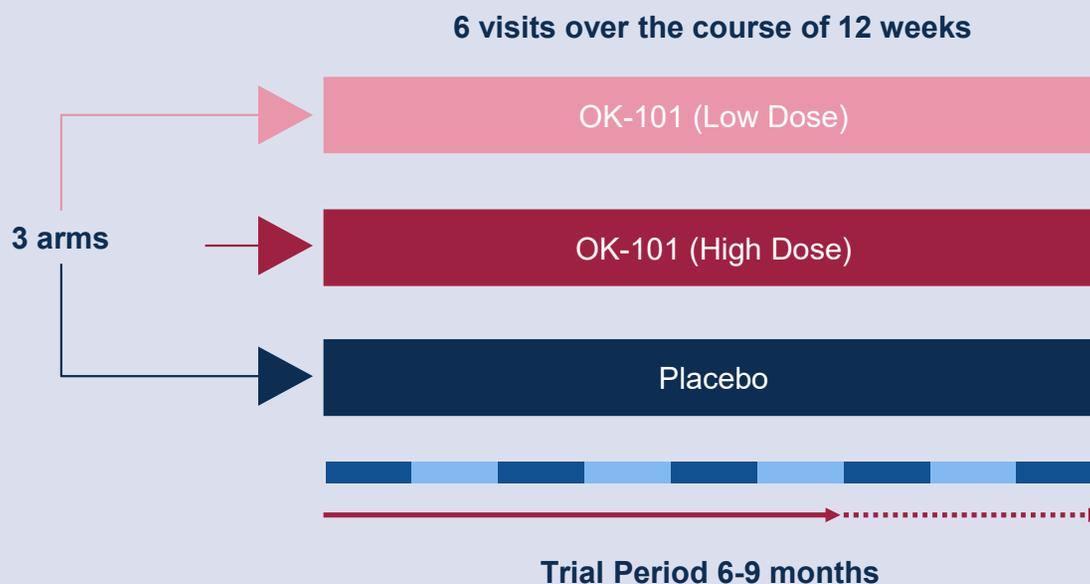
Primary Objective:

Compare safety and efficacy of OK-101 to placebo for the treatment of the signs and symptoms of dry eye

N=240 subjects

12 Weeks Dosing

Screening via
Controlled Adverse
Environment
Exposure to
Ascertain Eligibility



ENDPOINTS

Primary Endpoints (through Day 85)

- Total Corneal Staining (Sign)
- Ocular Discomfort Score (Symptom)

Secondary Endpoints

- Conjunctival Redness
- Schirmer's Test
- Tear Film Break-up Time (TFBUT)
- Ocular Surface Disease Index[®] (OSDI[®])
- Daily Symptom Diary

Patent Protection up to 2039

OK-101 Technology:

Composition of Matter: US 10,233,219

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

Dry Eye

- Method of Use: US 11,197,906
- Issued in US to 2037 with potential patent term extension up to 2041

Neuropathic Pain

- Method of Use: US11,254,720
- Issued in US to 2034 (+187 days of *PTA)

OK-201 Technology:

Composition of Matter: US 10,899,796

Issued in US to 2036 (+70 days of *PTA) with potential patent term extension up to 2042

Dry Eye, Pain, Inflammation

- Method of Use: US 10,899,796
- Issued in US to 2036 (+70 days of *PTA) with potential patent term extension up to 2042
- Issued European Patent on Comp. of Matter and Use for neuropathic pain, ocular pain, ocular inflammation, or dry eye: EP3373947

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.



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

Willy Simon

Non-Executive Director

International banking experience gained in senior leadership positions at multiple financial institutions.



Bernard Denoyer

Non-Executive Director

Extensive financial management experience as Senior Vice President of Synergy Pharmaceuticals, Inc. Also served as Chief Financial Officer and Senior Vice President of META Group, Inc.



John Brancaccio

Non-Executive Director

Financial executive with extensive international and domestic experience in pharmaceutical and biotechnology companies



Investment Highlights

- » Novel Molecule Targets Both Ocular Inflammation and Pain, Two Major Symptoms Underserved by Current Dry Eye Therapies
- » Addressing Unmet Need in ~\$6.5 Billion Market in Dry Eye Disease
- » Q1 2023 Phase 2 Trial Initiation. Anticipated Top Line Data in Q4 2023, with Potential for Accelerated Regulatory Submission
- » Patent Protected until 2039
- » Experienced Leadership



**Dry Eye Disease
and Ocular Pain**

OKYO Pharma Ltd.

14-15 Conduit Street

London W1S 2XJ

Tel: +44 (0) 207 495 237

OKYO Pharma U.S. Inc.

420 Lexington Avenue,

Suite 1402

New York, NY, 10170 USA

Tel: +1 (917) 225-9646

Nasdaq

OKYO

LSE

OKYO

info@okyopharma.com