

Targeting Dry Eye with OK-101



**OKYO
PHARMA**

Corporate Presentation

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OKYO Pipeline

Major OKYO focus: OK-101 to treat Dry Eye Disease

Asset	Indication	Pre-Clinical	*IND-Enabling Studies	Phase 1	Phase 2	Phase 3
OK-101	Dry Eye			**Not Required	Anticipated start date Q1-2023	
	Uveitis					
	Allergic Conjunctivitis					
	Ocular Pain					
OK-201	Discovery Program					

*Anticipated IND Submission date Q4, 2022

**Topical drug delivery

Investment Highlights

Topically Delivered OK-101 Drug Candidate

- **Novel mechanism of action:** anti-inflammatory & pain reducing activity
- Inflammation and pain are the most common symptoms of dry eye
- Strong need for new drugs for dry eye disease
- Huge market potential for new drugs for dry eye disease

Rapid Clinical Development

- IND planned for Q4 2022
- First human trial planned as Phase 2 efficacy trial in dry eye disease patients
- Phase 2 planned to enroll first patient in Q1 2023
- **Topline data anticipated in Q3, 2023**
- **Development time to approval: 4-5 years**

Capital Efficient Program

- **Able to skip Phase 1 safety trial** and go directly to Phase 2 safety and efficacy trial in dry eye disease patients
- Short Phase 2 trial: n = 200-250
Trial duration = 6-8 months
- Phase 2 trial designed as potential Phase 3 registration trial
- Rapid clinical development plan

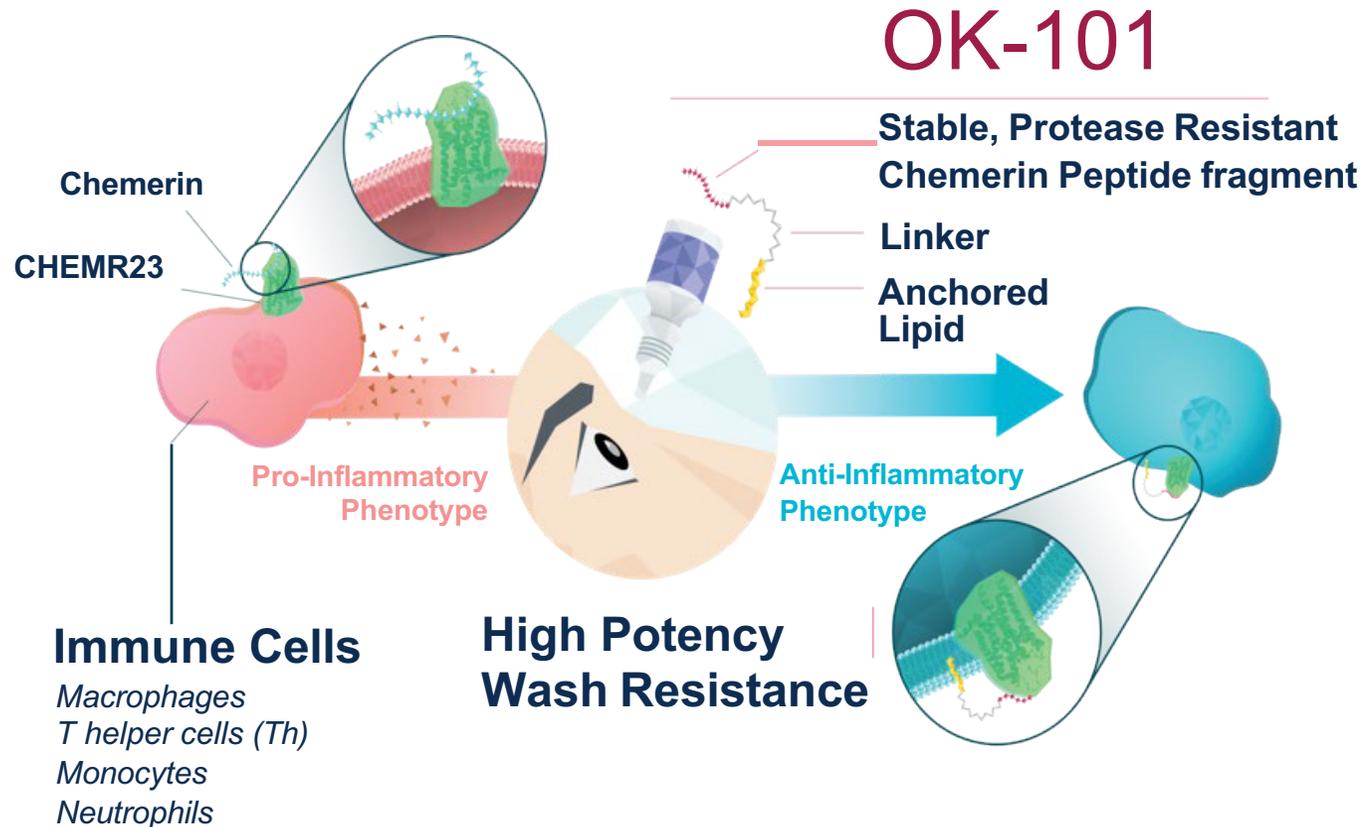
Drug Candidate OK-101 to Treat Dry Eye Disease

OK-101: *A lipid-conjugated chemerin peptide that targets a *GPCR receptor located on ocular immune cells involved in inflammation*

- *Novel mechanism-of-action – In vitro and animal studies indicate OK-101 exhibits both anti-inflammatory and ocular pain reducing activities*
- *Lipidated chemerin peptide chemistry minimizes tear washout from ocular surface*
- *Administered topically, and is planned to go straight from successful IND filing to Phase 2 efficacy trial in dry eye disease patients*
- *Rapid path to establishing efficacy - should save time and capital on clinical development*

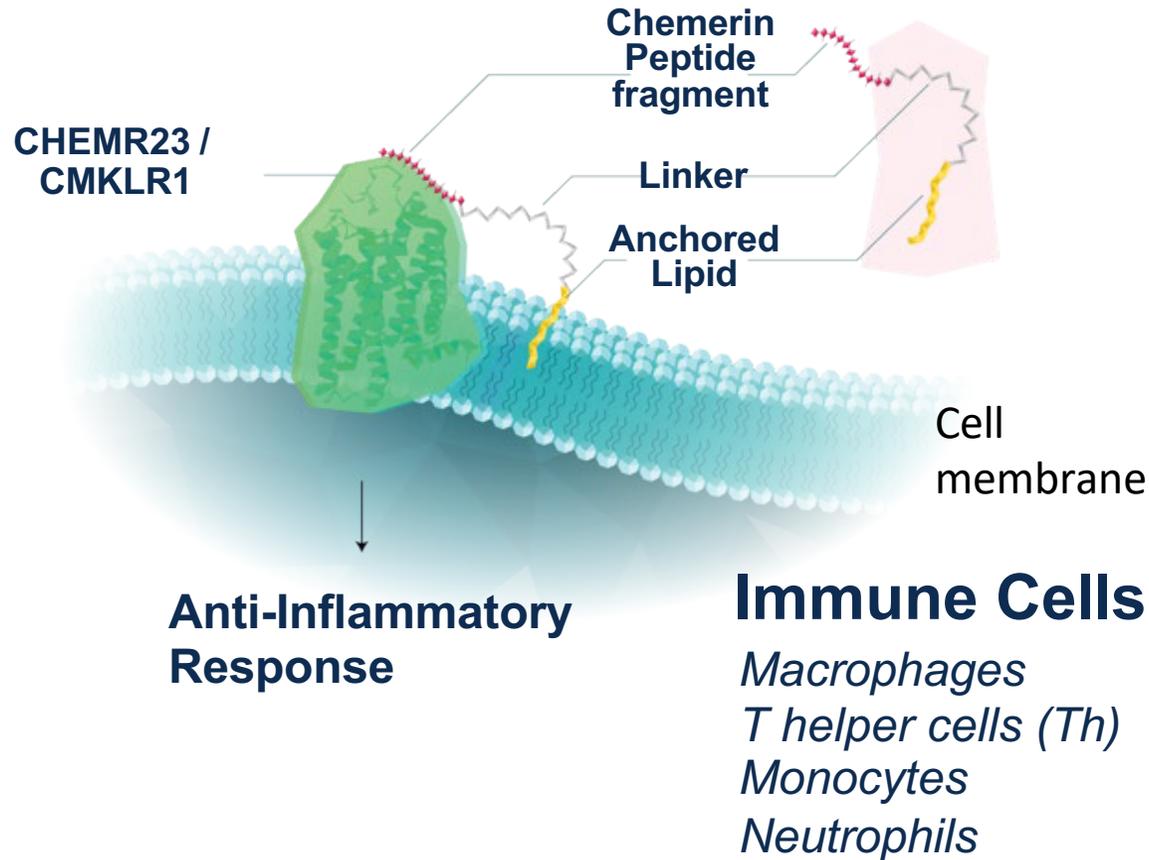
** G protein-coupled receptor*

Chemerin- A Potential Regulator of Inflammation & Pain



- Chemerin, endogenous agonist of chemerin receptor ChemR23, activates immune cells at the inflammation site
- Smaller chemerin derived peptides can physiologically inhibit the inflammatory response of chemerin
- Topically administered OK-101 peptide can dramatically enhance the anti-inflammatory response

Proprietary MAP platform



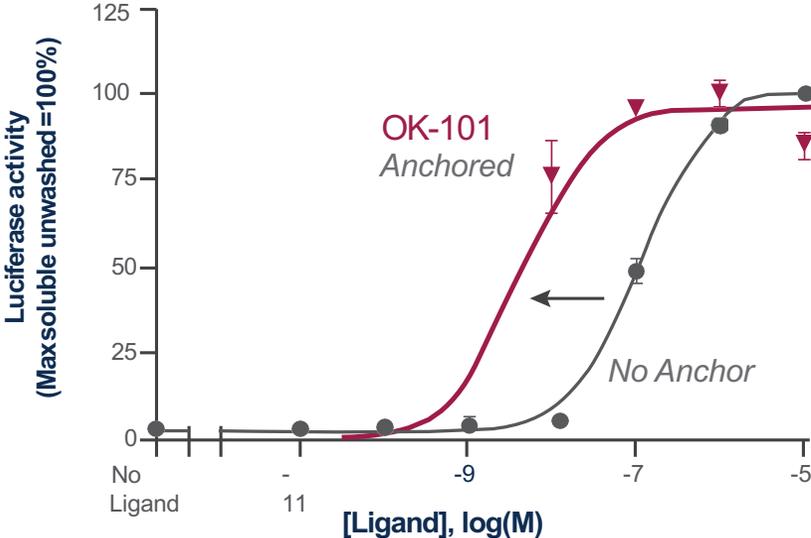
Novel membrane-anchored peptide (MAP) technology* enhances potency and increases drug residual time on the ocular surface

**OKYO has exclusive license for OK-101, a novel membrane-anchored chemerin peptide from OTTx Therapeutics, Boston that has potential to reduce ocular surface inflammation and ocular pain*

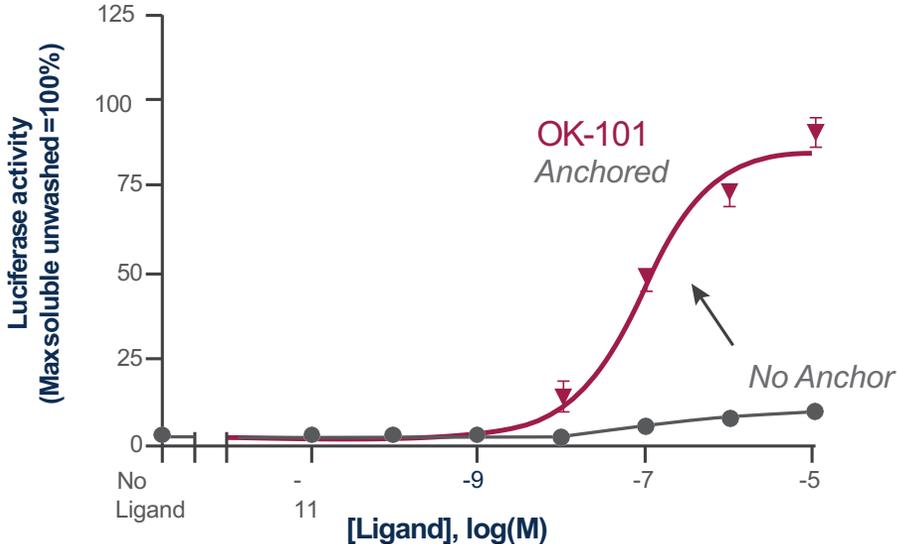
Membrane Anchoring Improves Potency, and Durability

**In-vitro studies*

Enhanced Potency Human Chemerin Receptor

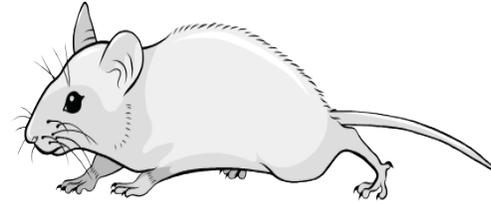
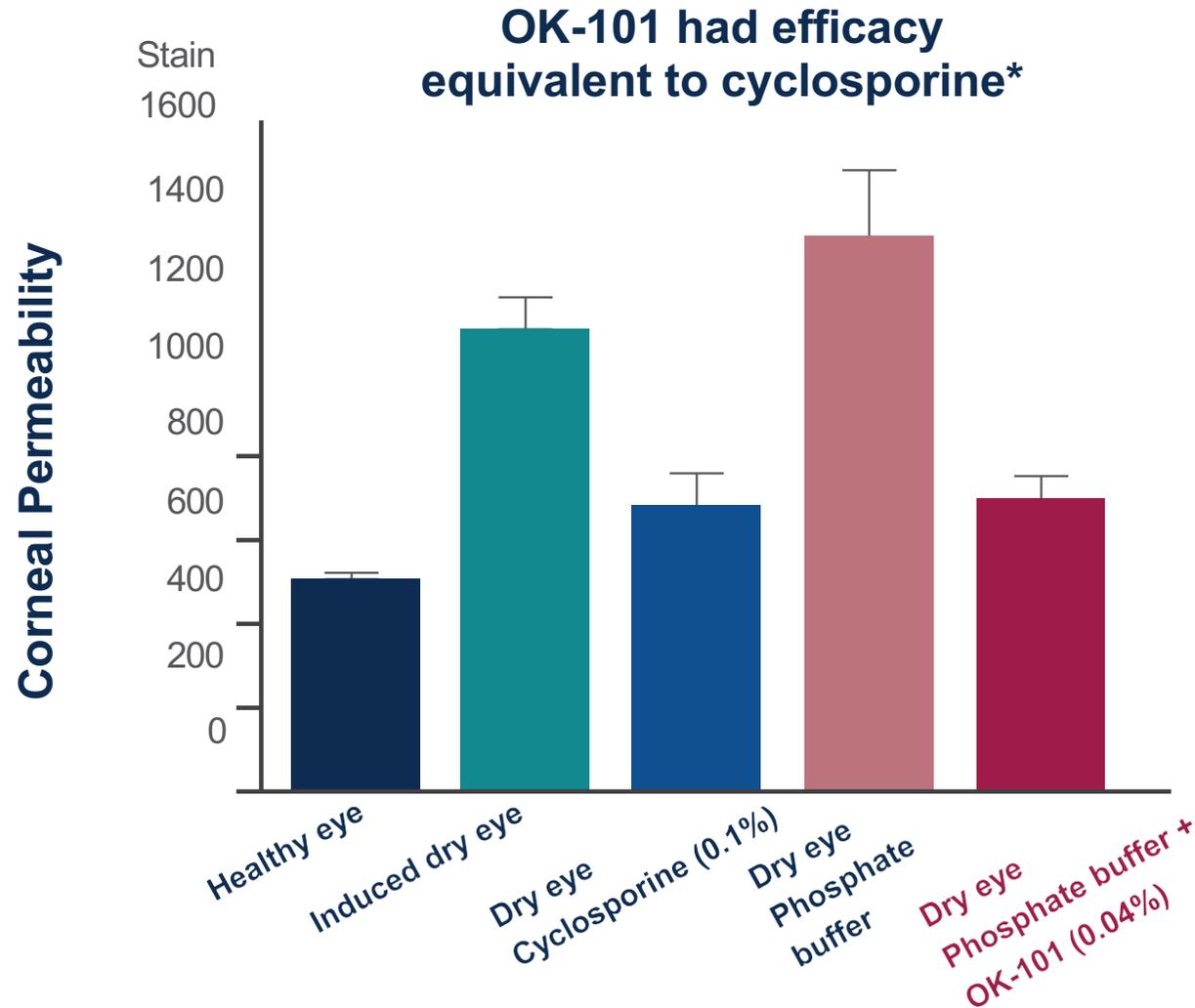


Increased Durability Human Chemerin Receptor (Wash Resistant)



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

Validation, Dry Eye Mouse Model



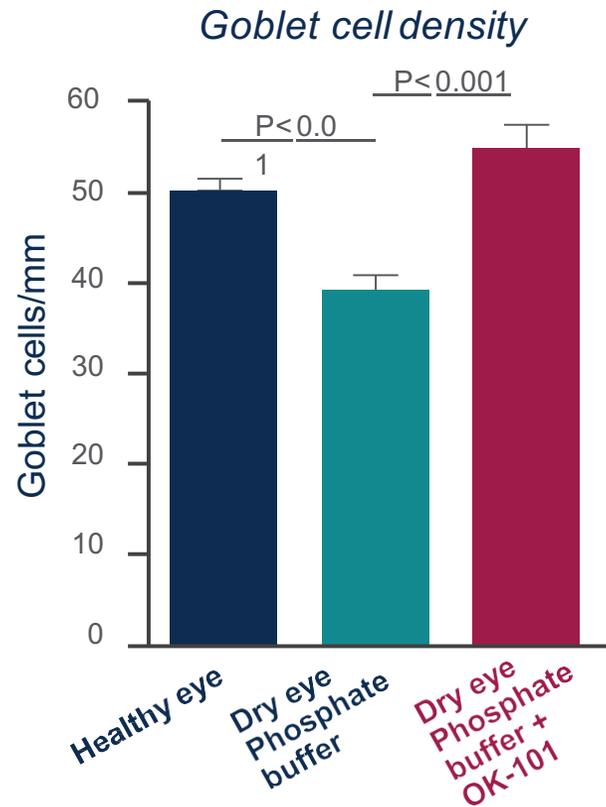
- OK-101 and cyclosporine were administered topically twice a day
- Corneal permeability significantly reduced with OK-101 vs phosphate buffer (vehicle) alone
- Potency of OK-101 was comparable to cyclosporine, an active ingredient of Restasis (Allergan)
- Reducing corneal permeability with OK-101 improves 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

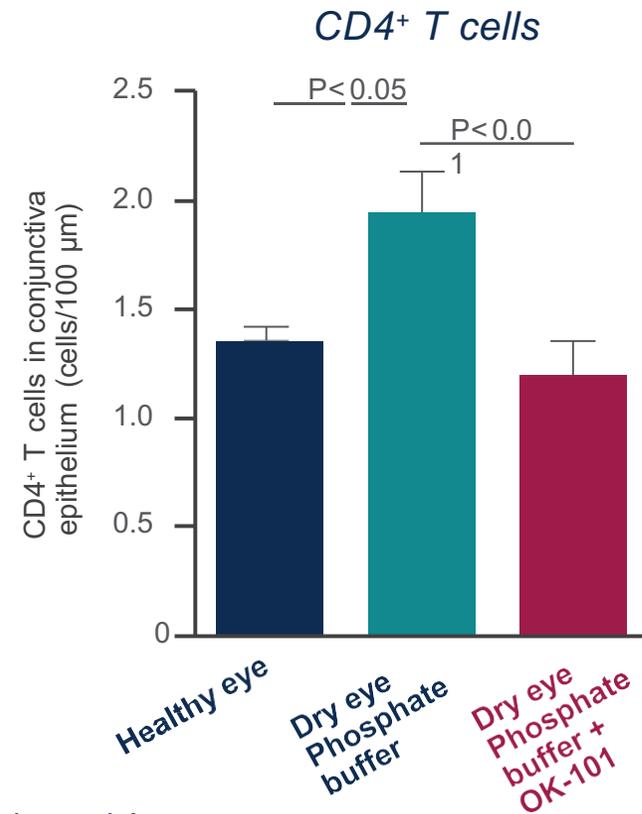
Increased mucin-secreting goblet cells*

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



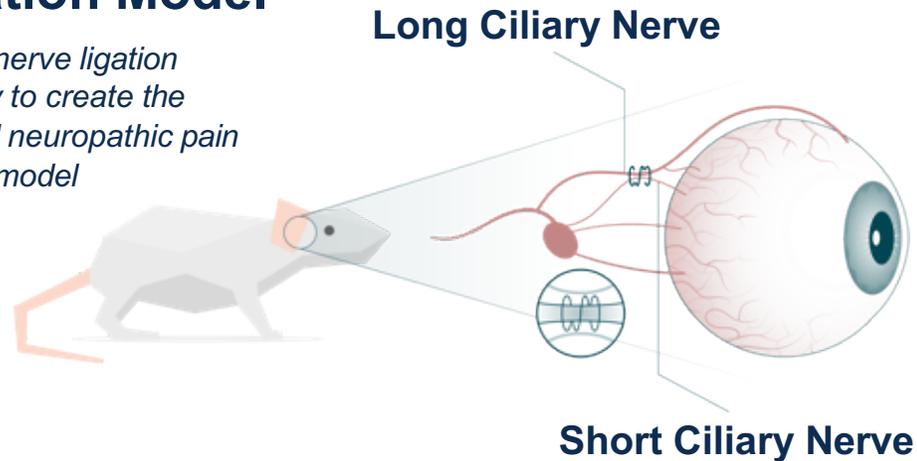
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OK-101: Potential Modulator of Ocular Pain

A significant proportion of dry eye patients suffer from “neuropathic ocular pain” with moderate to greater pain intensity.

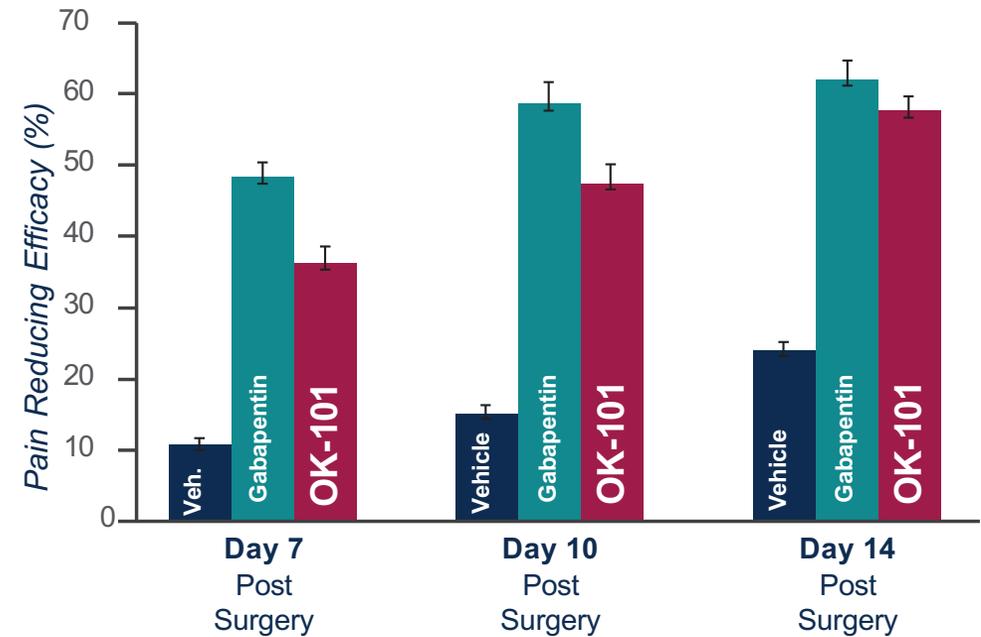
* Ciliary Nerve Ligation Model

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), a commonly used drug for neuropathic pain



¹Topical administration (0.04%) 6 times daily

²Administered by intraperitoneal injection, 100 mg/kg once at Day 4, 7, 10, and 14)

Dry Eye Disease: Overview

~700,000,000

Worldwide patients

~20,000,000

US patients

~34%

+50 yrs old affected



Source: Papas et al. Ophthalmic Physiol Opt. 2021;41:1254
Aggarwal & Galor. 2018 F1000Research, 7:1952
Farrand et al. AJO. 2017;182:90
Dana et al, AJO 2019,202:47

Ocular Surface Damage

Lack of moisture and lubrication resulting in progressive damage to the ocular surface

Inflammation & Hyperpermeability

Inflammation and hyperpermeability leads to chronic symptoms of pain, itchiness, burning, and potential visual impairment

Dry Eye Disease Growth & Digital Screen Time

Long-term use of contact lenses and increasing digital screen time means the incidence of dry eye disease will continue to grow

Dry Eye Disease (DED) Market Opportunity

- Global DED* market approximately \$5.22 billion in 2019 and expected to reach \$6.54 billion by 2027.
- DED causes approximately \$3.8 billion annually in healthcare costs and represents a major economic burden to public healthcare, accounting for more than \$50 billion† to the US economy annually.
- Present-day drugs inadequately treat DED - arguing that a drug that is more effective will further increase market size.

* Market Research Report, Dry Eye Syndrome Market, FBI102413, Dec. 2020

† Yu J et al, Cornea. 2011; 30: 379

Dry Eye: Standard of Care & Short Comings of Current Treatments

5 FDA approved drugs on market

¹ Comments

Restasis

(0.05% cyclosporine)
Allergan

Delayed response, up to 6 months to improve symptoms, burning sensation when instilled

² **70.8% patients do not refill Rx at Month 12**

Xiidra

(5% LFA-1 antagonist)
Novartis

Eye irritation and burning sensation, change in taste

² **64.4% patients do not refill Rx at Month 12**

Cequa

(0.09% Cyclosporine)
Sun Pharma

Burning, pain upon instillation, blurry vision, UTI (side effects on label)

Eysuvis

(0.25% Loteprednol)
Kala Pharma

Short-term treatment only (maximum 2 weeks)

Tyrvaya

(0.03 mg Varenicline/ inhalation)
Oyster Point

Sneezing, cough & throat irritation (side effects on label)

Short Comings of Current Drugs

- Inadequate efficacy
- Slow onset of action
- Several side effects of current drugs demand the need for more effective drugs to treat dry eye disease

The need for more effective drugs

¹ Side Effect profiles from Drug Labels, ² White DE, et al. Clinical Ophthalmology 2019:13 2285

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Drug Development Timelines

*Average time from drug discovery through clinical development to FDA approval: >10 years

Standard development:
Orals/injectables

IND → Phase 1 (volunteers) → Phase 2a/2b safety/efficacy → Phase 3 2 registration trials → NDA FILING → FDA Approval ~ 1 year after NDA

Standard development:
Topical drugs

IND → Phase 2a/2b safety/efficacy → Phase 3 2 registration trials → NDA FILING → FDA Approval ~ 1 year after NDA

OK-101:
Topical drug

IND → Phase 2 safety/efficacy → Phase 3 1 or 2 registration trials → NDA FILING → FDA Approval ~ 1 year after NDA

Potential Registration Trial ↗

Potential OK-101 Development time to approval: 4 - 5 years

* PhRMA, Biopharmaceutical Research & Development: The Process Behind New Medicines (Washington, DC: PhRMA, May 2015)

OKYO Pharma announces Successful Completion of a Pre-IND Meeting with the FDA on the Development of OK-101 to Treat Dry Eye Disease

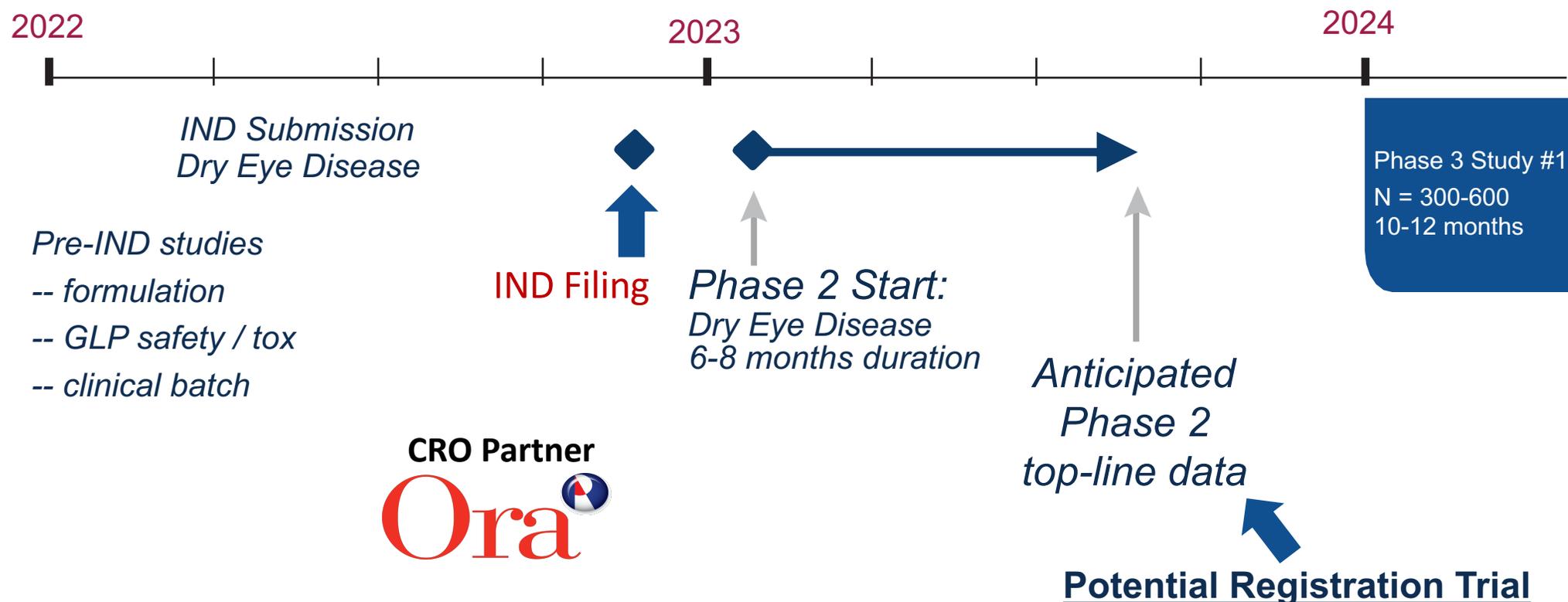
OK-101 First-in-Human Trial planned as Phase 2 Trial incorporating Primary Efficacy Endpoints covering Signs and Symptoms of Dry Eye Disease

Key points from press release:

- FDA concurred with OKYO's plan to pre-specify co-primary efficacy endpoints covering both a sign and symptom of dry eye disease in the planned DED Phase 2 clinical trial.
- Successful Phase 2 trial with pre-specified primary efficacy endpoints would accelerate timeline to new drug application (NDA).

OK-101 Development Timeline

- Skipping Phase 1
- Designing Phase 2 effectively as a Phase 3 registration trial



Topically Delivered OK-101 Drug Candidate

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Intellectual Property Portfolio

OK-101 Technology:

Comp. 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)

*PTA = patent term adjustment for delay in patent office

OK-201 Technology:

Comp. 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 and BBC Worldwide



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





OKYO
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Dry Eye Disease and Ocular Pain

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