

Clinical Development
of Urcosimod to Treat
Neuropathic Corneal
Pain



Nasdaq: OKYO

**Corporate
Presentation**

JUNE 2025

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Urcosimod: 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 for DED cleared by FDA	December 2022
240 patient DED trial began	May 2023
Top Line data released	Jan 8, 2024
48 patient NCP trial began	Oct 23, 2024

CMKLR1 Receptor (ChemR23)

Modulates

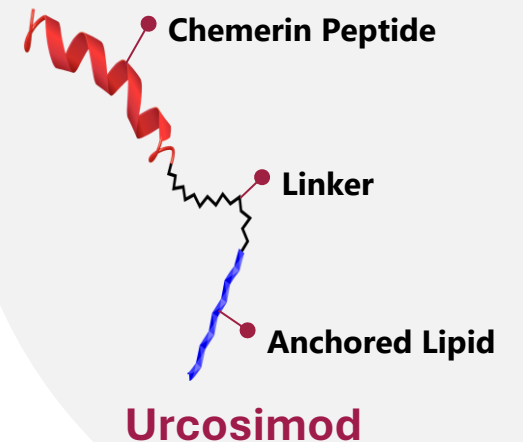
Inflammation
pain

Receptor localization

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

Endogenous ligand

Chemerin: 136 aa peptide



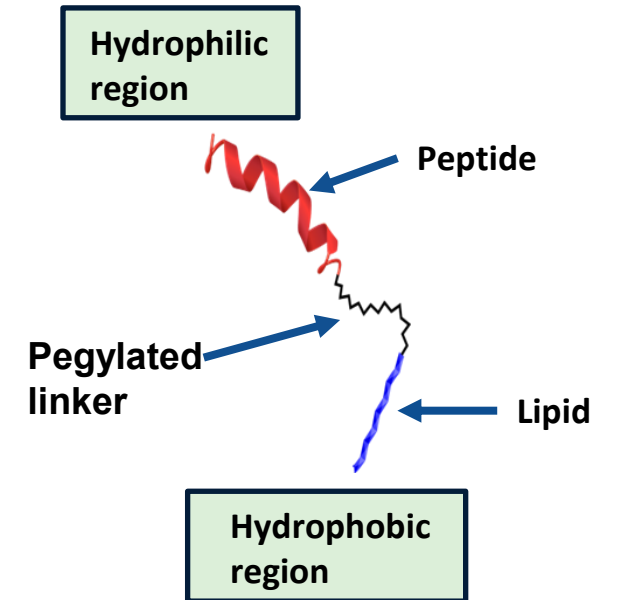
ESTABLISHING USAN (e.g., GENERIC) NAME FOR OK-101

USAN COUNCIL CONFIRMED NAME: **urcosimod**

NAME OFFICIAL ON JANUARY 29, 2025

Transitioned to urcosimod for all future communications
and on website with language to acclimate the reader

[e.g., “**urcosimod (formerly OK-101)**”]

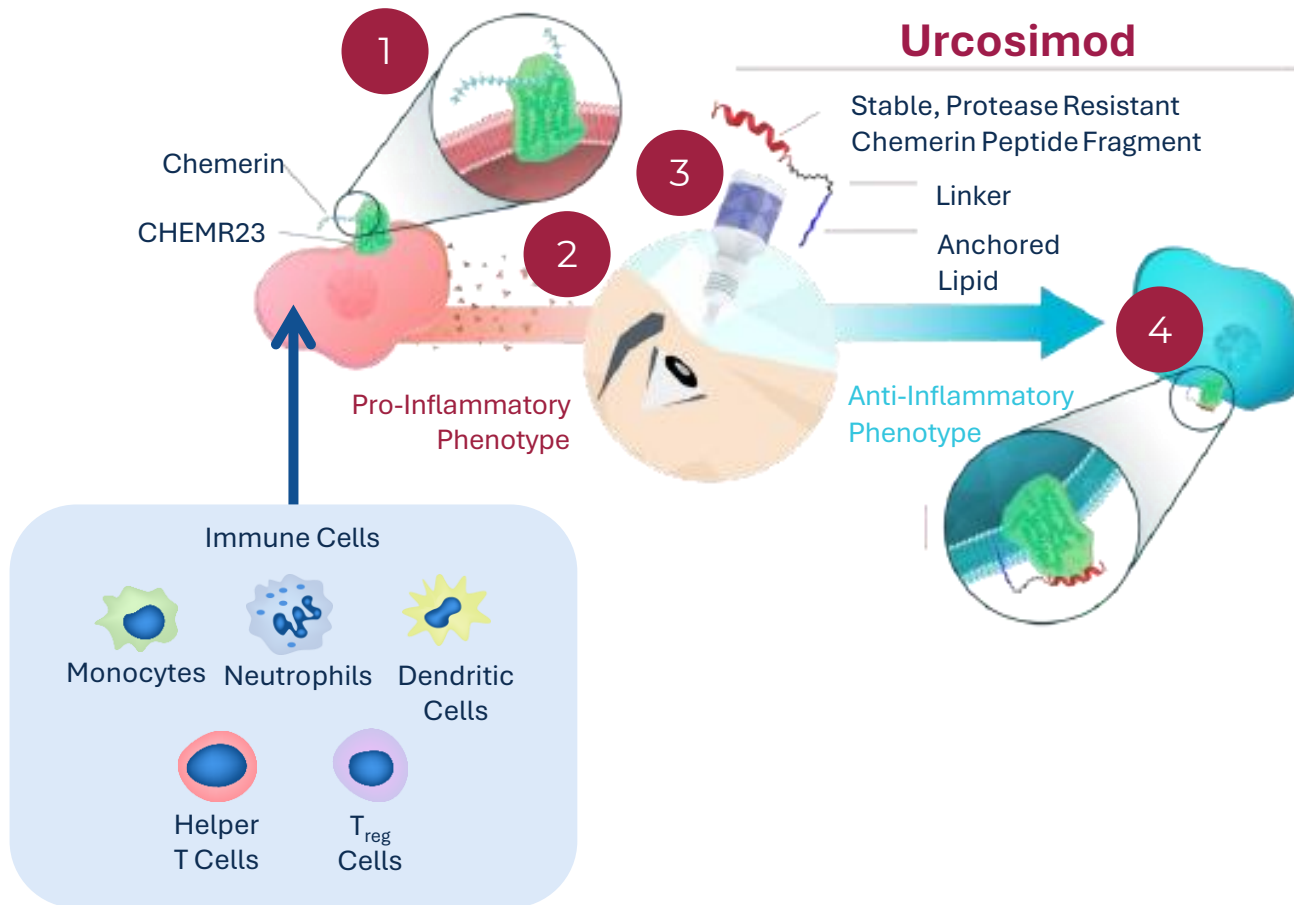


Pipeline Focus: Urcosimod to Treat Ocular Diseases

Indication	Pre-clinical	Phase 1	Phase 2	Phase 3
OK-101				
Dry Eye Disease (“DED”)	Phase 2 Trial Completed			
Neuropathic Corneal Pain (“NCP”)	Phase 2 Trial Initiated in Q4 2024			
Allergic Conjunctivitis				
Uveitis				

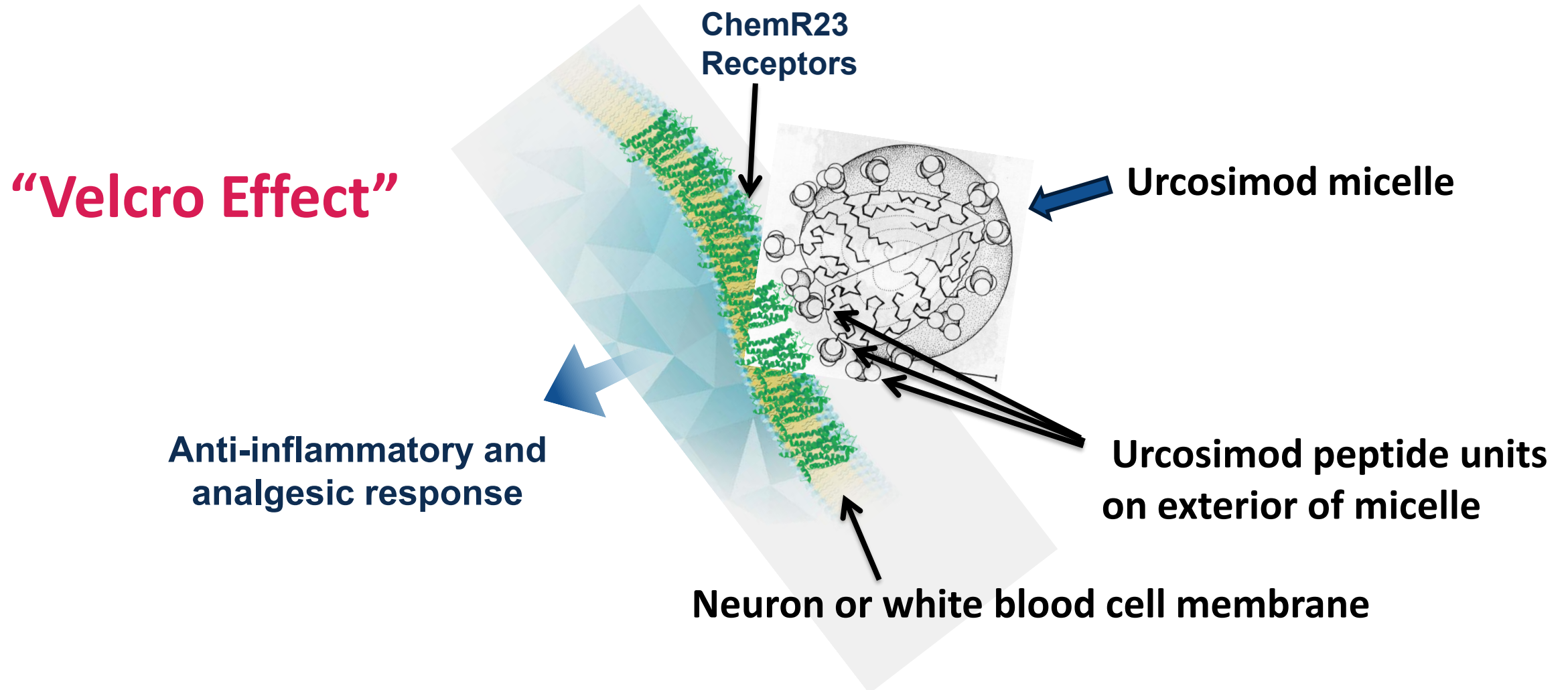
Urcosimod Nonclinical Studies

Chemerin Derived Peptide: A Potential Regulator of Inflammation & Pain



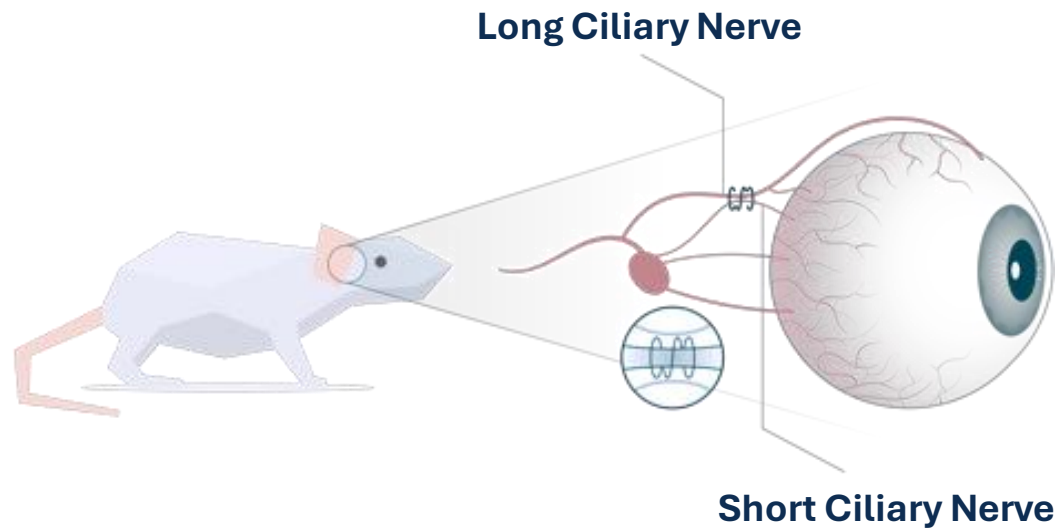
- 1 Pro-inflammatory chemerin activates immune cells at the inflammation site
- 2 Peptides derived from chemerin physiologically inhibit the inflammatory response
- 3 The data suggests that topically administered urcosimod peptide can dramatically enhance the anti-inflammatory response
- 4 Proprietary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

Urcosimod: Targeting ChemR23 Receptors



Urcosimod Reduced Neuropathic Corneal Pain (NCP) in Mouse Model*

Ciliary Ligation Model* Illustrates Urcosimod's Potential to Reduce Ocular Pain. Ciliary nerve ligation surgery to create the neuropathic corneal pain (NCP) model

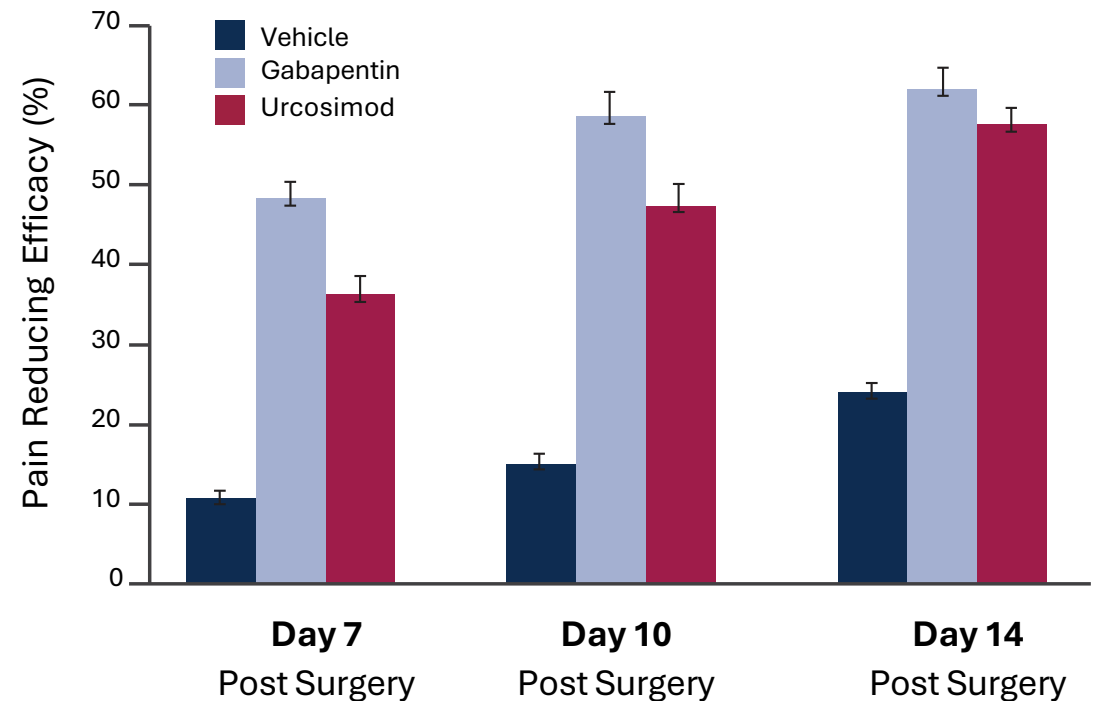


* Collaboration with Dr. Pedram Hamrah, Tufts Medical Center, Boston (Kenyon B, ARVO Abstract 4085, 2020)

** Topical administration (0.04%)

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

Urcosimod** Reduced Corneal Pain Response Comparable to Gabapentin*** (GBP)



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 urcosimod is also expressed on neurons and glial cells in the dorsal root ganglion and spinal cord

Benefit from a drug that comprises anti-inflammatory and neuropathic pain reducing characteristics

Urcosimod: a potentially promising candidate for the treatment of both inflammation and pain



Urcosimod to Treat Neuropathic Corneal Pain (NCP)

Urcosimod to Treat Neuropathic Corneal Pain (NCP)

» Agreement with Tufts Medical Center for NCP Phase 2 Trial Announced in July 2023

» NCP Trial 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 Initiated in October 2024

Urcosimod Trial to Treat Neuropathic Corneal Pain

Phase 2a, Randomized, Double-Masked, Placebo-Controlled Study Assessing the Safety and Efficacy of Urcosimod in Subjects with Neuropathic Corneal Pain
IND Clearance by FDA - February 2024

Primary Endpoint:

To evaluate the efficacy of urcosimod compared to placebo instilled QID in subjects with neuropathic corneal pain, assessed by visual analogue scale (VAS).

Study Population:

A total of 54 subjects to be screened to ensure that **48 subjects** (16 per arm) are enrolled for 12 weeks of treatment

Study Duration:

17 weeks, including a visit 1 week before the starting date (Visit 1) and 12 weeks of treatment and an End of Study visit at 16 weeks. The trial anticipated to run for 9-12 months.

OKYO Pharma Announces First Patient Dosed with OK-101 in the First Clinical Trial to Treat Neuropathic Corneal Pain

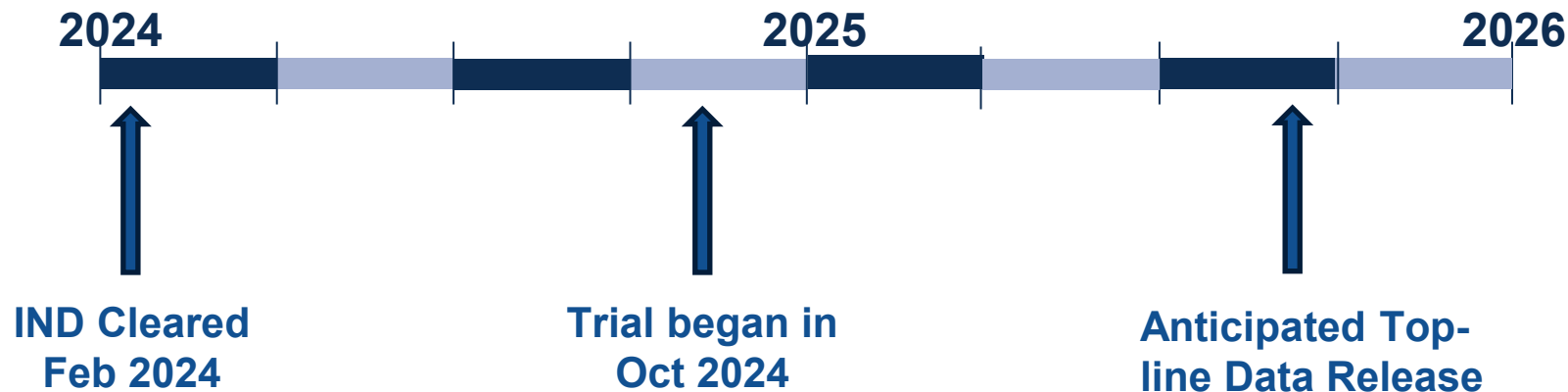
- *OK-101 is the first drug candidate to enroll patients in a clinical trial specifically diagnosed with this disease*
- *The Phase 2 trial is designed as a randomized, placebo-controlled, double-masked study to treat 48 NCP patients*
- *OK-101 is the first IND granted by FDA to treat patients with NCP*

London and New York, NY, October 23, 2024 – OKYO Pharma Limited (NASDAQ: OKYO), an ophthalmology-focused bio-pharmaceutical company which is developing OK-101 to treat corneal neuropathic pain (NCP)), an ocular condition associated with pain but without an FDA-approved therapy, is pleased to announce that the first patient has been dosed in the Phase 2 trial of topical ocular OK-101 to treat NCP.

Phase 2 Trial for Urcosimod (formerly called OK-101) to Treat NCP

**Phase 2, Randomized, Double masked, Placebo-Controlled Study
Assessing Safety and Efficacy of Urcosimod (formerly called OK-101) in
Subjects with NCP**

- Number of subjects to be enrolled: 48
- Number of Cohorts: three (0.05% and 0.1% Urcosimod and Placebo)
- Number of subjects per cohort: 16
- Visits: Five visits over the course of 16 weeks
- Study duration: 9-12 months
- Principal Investigator: Pedram Hamrah, MD, Tufts Medical Center, Boston, MA



OKYO Pharma Announces Plans to Accelerate the Clinical Development of Urcosimod to Treat Neuropathic Corneal Pain

- *Urcosimod phase 2 trial treating Neuropathic Corneal Pain (“NCP”) patients was initiated in October 2024 and designed as a double-masked, randomized, 12-week placebo-controlled trial.*
- *OKYO Pharma plans to analyze the efficacy data from the 17 patients who have now completed the Phase 2 trial.*
- *OKYO Pharma plans for a meeting with FDA following evaluation of clinical data.*

London and New York, NY, April 30, 2025 – OKYO Pharma Limited (NASDAQ: OKYO), an ophthalmology-focused biopharmaceutical company which is developing urcosimod (formerly called OK-101) to treat NCP, an ocular condition associated with chronic and often severe pain but without an FDA-approved therapy, announces plans to accelerate the clinical development of urcosimod to treat NCP through the analysis of its data following the early closure of its Phase 2 trial.

RATIONALE FOR CLOSING THE TRIAL EARLY

- **Decision to close trial after 17 patients completed the study due to strong desire to access the currently masked data.**
- **Company anticipates analysis of data from these patients should take no longer than 8-10 weeks.**
- **Decision to close the trial enables significant cut in time to FDA end-of-phase 2 meeting to explore accelerated plans for drug's further clinical development.**
- **Number of patients completing trial requested compassionate use which we are seeking to arrange with Tufts Medical Center, subject to the necessary FDA approval.**

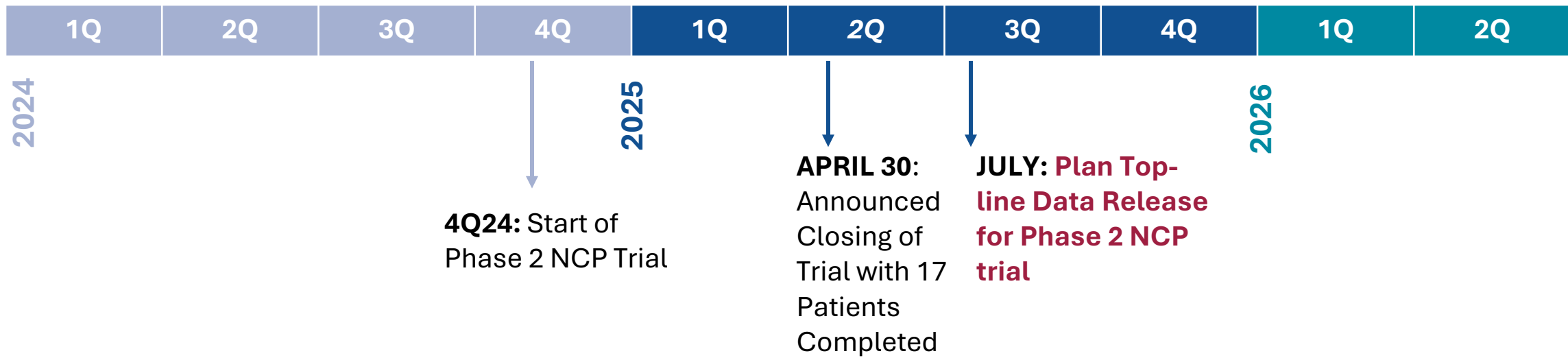
FDA Grants OKYO Pharma Fast Track Designation to Urcosimod for Neuropathic Corneal Pain

- **Fast Track designation by the FDA is granted to facilitate development and expedite review of therapies that aim to treat serious conditions and fulfill unmet medical needs.**
- **Designation intended to accelerate availability of new treatments to patients, providing earlier access to potentially beneficial therapies.**
- **Fast Track designation provides key benefits, including more frequent meetings with the FDA to discuss the drug's development plan, eligibility for Accelerated Approval and Priority Review if relevant criteria are met, and a potential Rolling Review of the New Drug Application (NDA).**

London and New York, NY, May 1, 2025. OKYO Pharma Limited (NASDAQ: OKYO), an ophthalmology-focused bio-pharmaceutical company which is developing urcosimod (formerly called OK-101) to treat NCP, an ocular condition associated with chronic and often severe pain but without an FDA-approved therapy, announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to urcosimod for the treatment of neuropathic corneal pain (NCP).

Company Catalysts

Urcosimod NCP Program



Patent Protection Through at Least 2039

Urcosimod Intellectual Property:

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

**Method of 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

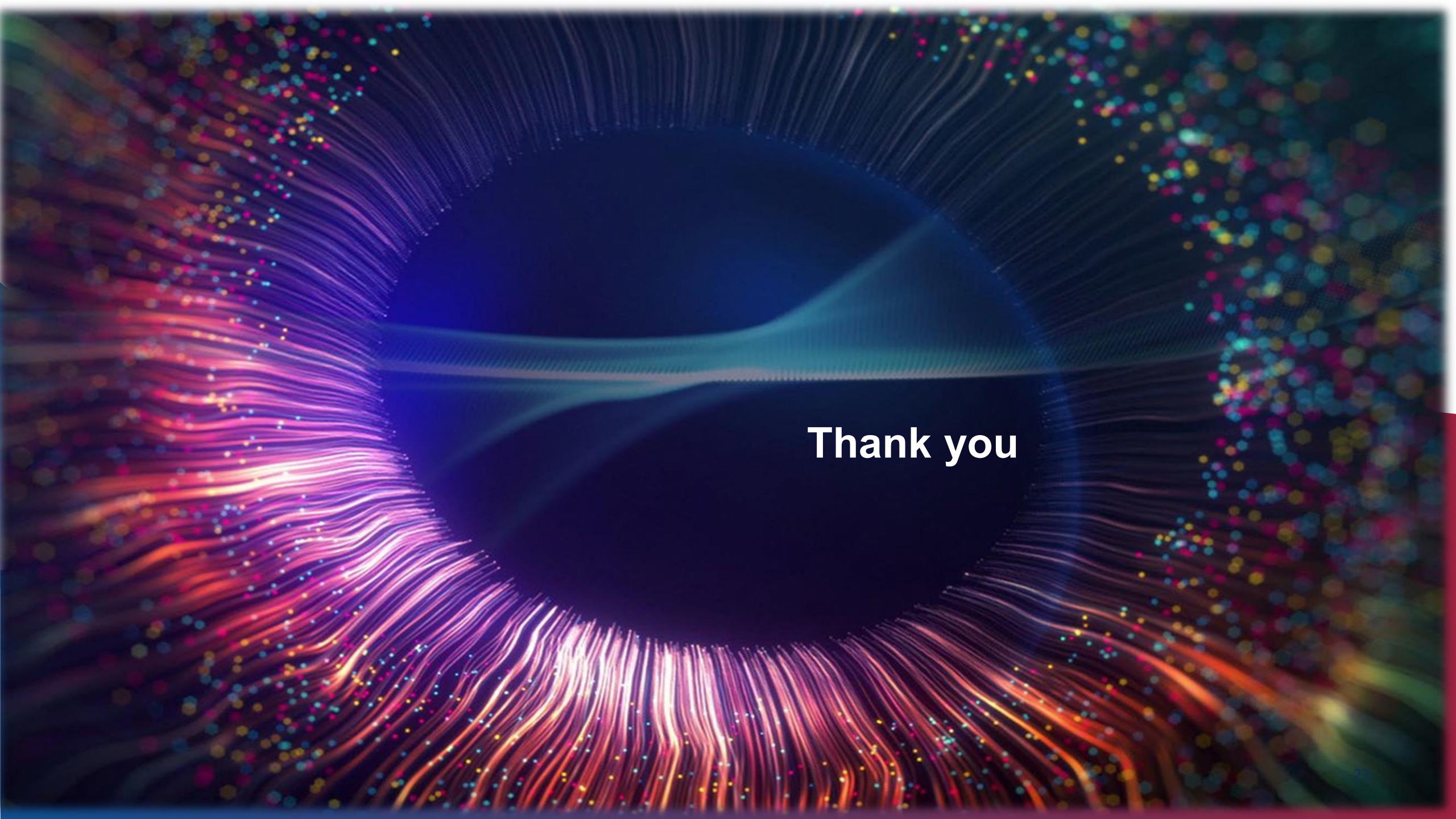


Willy Simon, Non-Executive Director International banking experience gained in senior leadership positions at multiple financial institutions.



Key Takeaways

- **Urcosimod** (formerly called OK-101) is a novel topical eye drop that targets both inflammation and ocular pain
- Neuropathic corneal pain (NCP) is characterised by heightened experience of pain in response to normally non-painful stimuli, which severely impacts quality of life
- No FDA approved therapy available for NCP
- **Urcosimod** Phase 2 trial for NCP initiated on October 23, 2024
- A recently completed **urcosimod** phase 2 trial in DED demonstrated improvement in symptoms associated with DED, including ocular pain, as well as *via* patient-reported diaries
- An FDA approved drug for NCP would undeniably create a considerable market opportunity for this unmet medical need
- Experienced leadership team & patent protection until 2039 and beyond
- History of frequent M&A activity in ophthalmology space



Thank you