Urcosimod to Treat Neuropathic Corneal Pain – A Major Unmet Medical Ocular Need

OKYO PHARMA

Nasdaq: OKYO

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URCOSIMOD To Treat NCP

OKYO is pioneering the first drug to treat this devastating ocular condition where there is no FDA-approved drug to treat NCP.

Have Fast-Track designation from FDA to treat NCP.

Only drug to have an IND from FDA to treat NCP.

First drug to successfully complete phase 2 trial in patients specifically diagnosed with NCP, and with positive efficacy results.

Urcosimod: A Lipid-Conjugated Chemerin Peptide

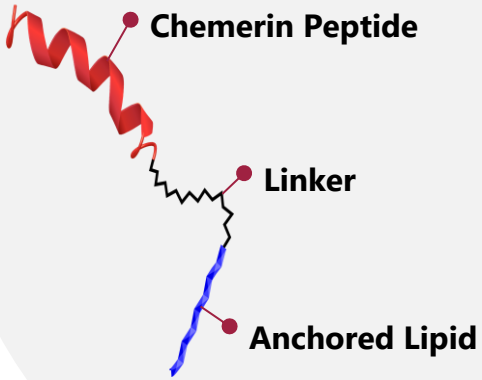
Drug candidate with anti-inflammatory and ocular pain reducing properties

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



Urcosimod

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

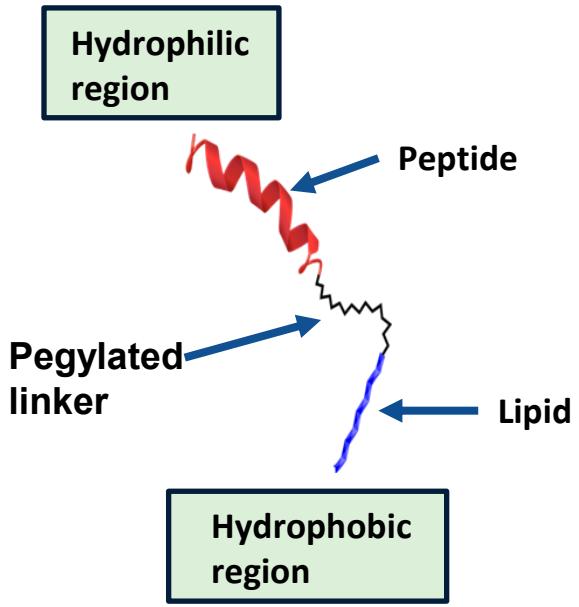
ESTABLISHING USAN (e.g., GENERIC) NAME FOR OK-101

USAN COUNCIL CONFIRMED NAME: **urcosimod**

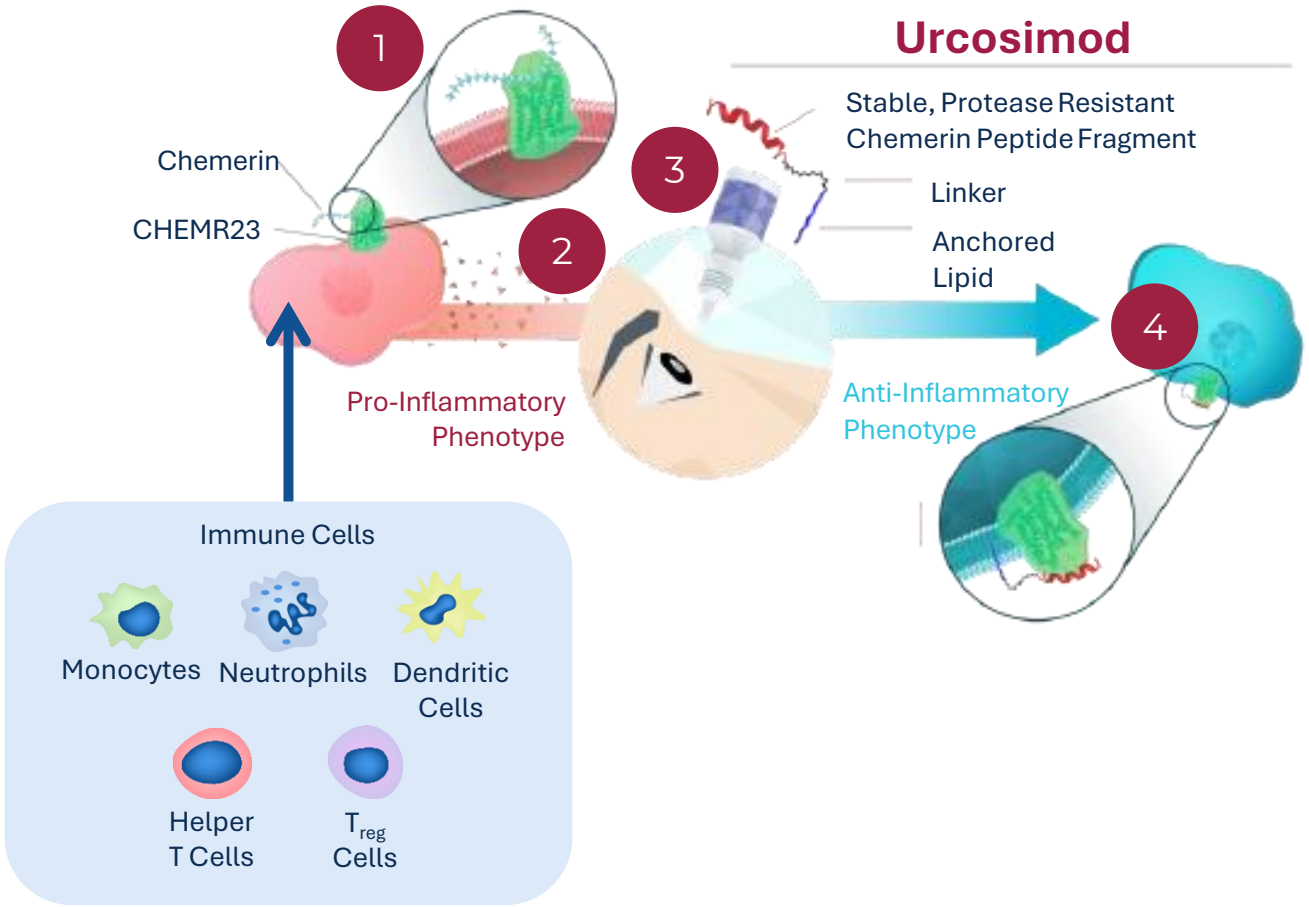
NAME OFFICIAL ON JANUARY 29, 2025

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

[e.g., "urcosimod (formerly OK-101)"]



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

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

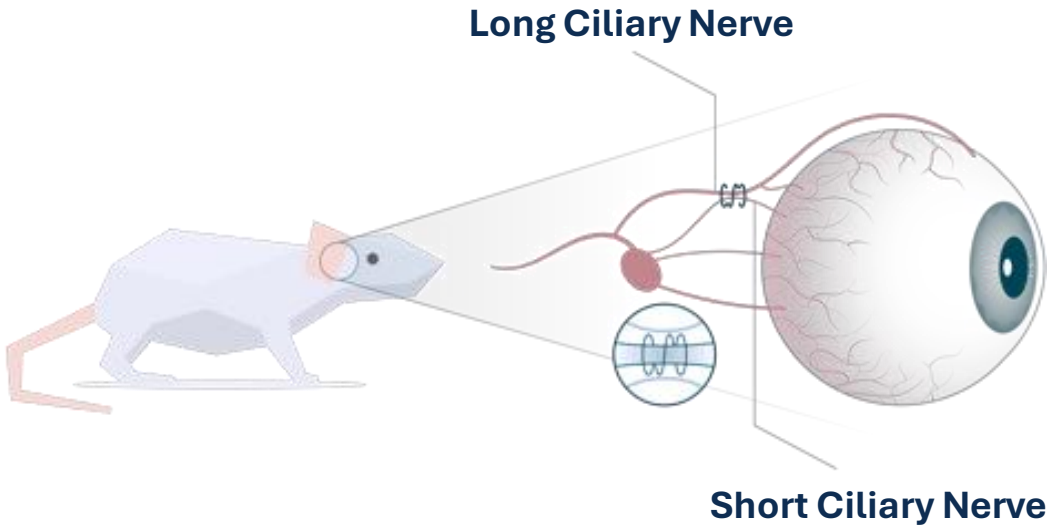
ChemR23 receptor on leukocytes targeted by urcosimod is also expressed on neurons and glial cells in the dorsal root ganglion and spinal cord

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

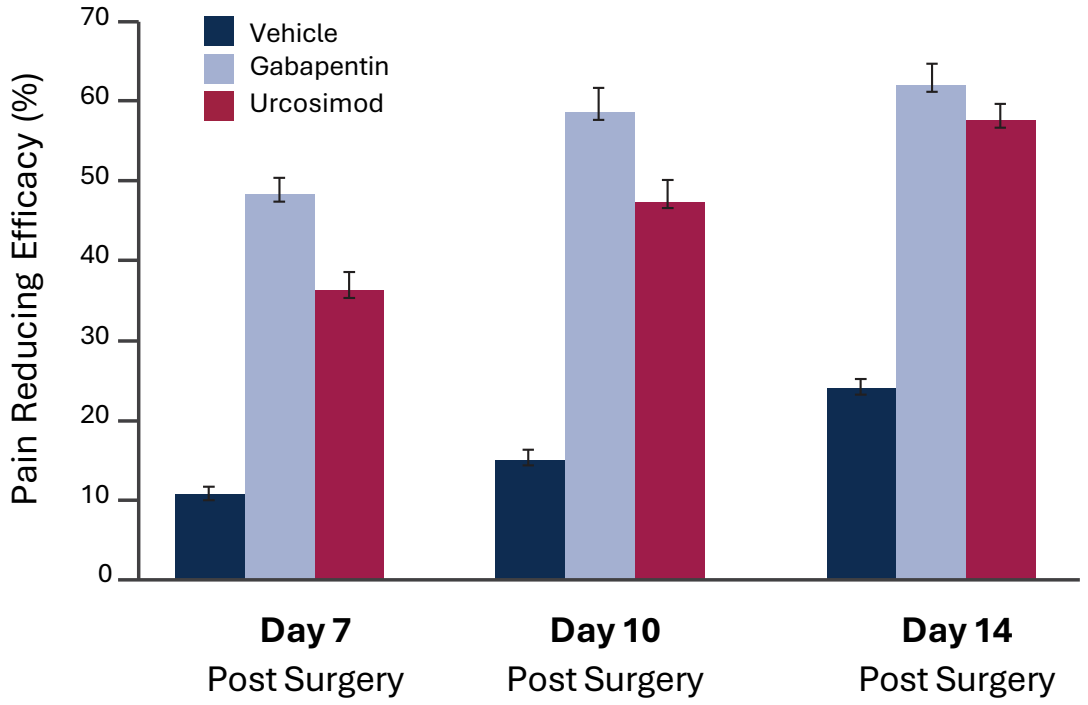
Urcosimod: a potentially promising candidate for the treatment of both inflammation and pain

Urcosimod 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



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



*** 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**

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

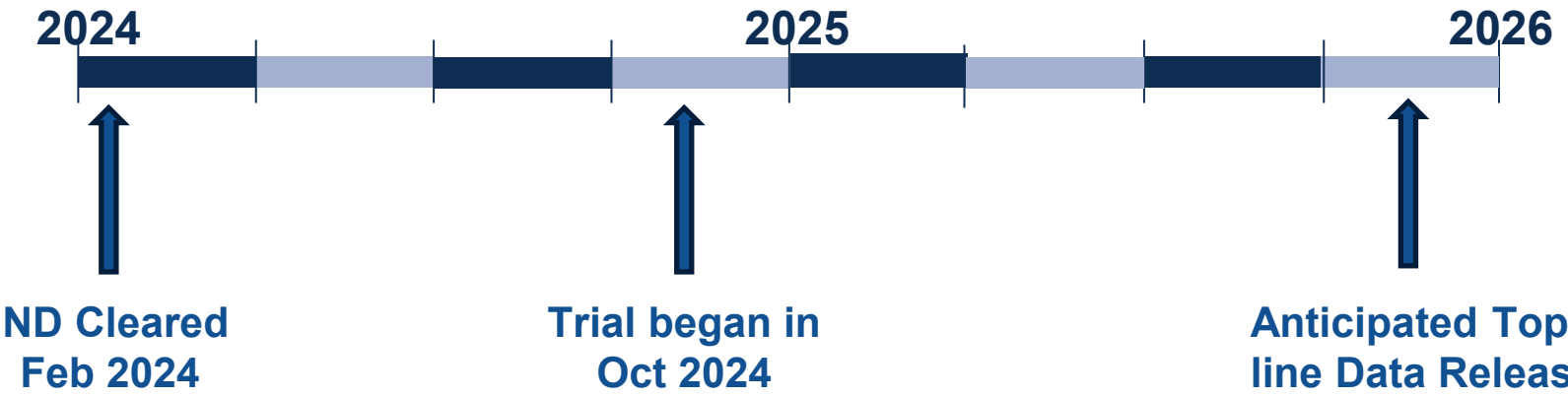
- ***OK-101 is the first drug candidate to enroll patients in a clinical trial specifically diagnosed with this disease***
- ***The Phase 2 trial is designed as a randomized, placebo-controlled, double-masked study to treat 48 NCP patients***
- ***OK-101 is the first IND granted by FDA to treat patients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

Urcosimod NCP Press Release – July 16, 2025 – Bullet Statements

- After 12 weeks of treatment, 75% of per-protocol patients receiving 0.05% urcosimod showed greater than 80% reduction in neuropathic corneal pain (NCP), as measured by Visual Analogue Scale (VAS), demonstrating highly effective treatment.
- Urcosimod (0.05%) demonstrated a marked reduction in pain scores as early as Week 4, with sustained efficacy maintained throughout the trial.
- A statistically significant reduction in mean pain scores was observed from Visit 1 to the end of treatment Visit 4 (p-value = 0.025) in the per-protocol 0.05% urcosimod group, indicating the drug's effectiveness over the study period.
- Notably, all these responders entered the study with moderate to severe NCP pain scores despite prior use of maximum medical therapy.
- No serious adverse events were reported among the 18 patients throughout the trial.

IMMEDIATE PLANS FOR URCOSIMOD'S FURTHER DEVELOPMENT

Multiple Ascending Dose (MAS) Phase 2 Trial in NCP Patients

- Randomized, placebo-controlled, double-masked trial in ~120 patients.
- Demonstrate statistical significance in reducing VAS pain score.
- Identify future registration dose.

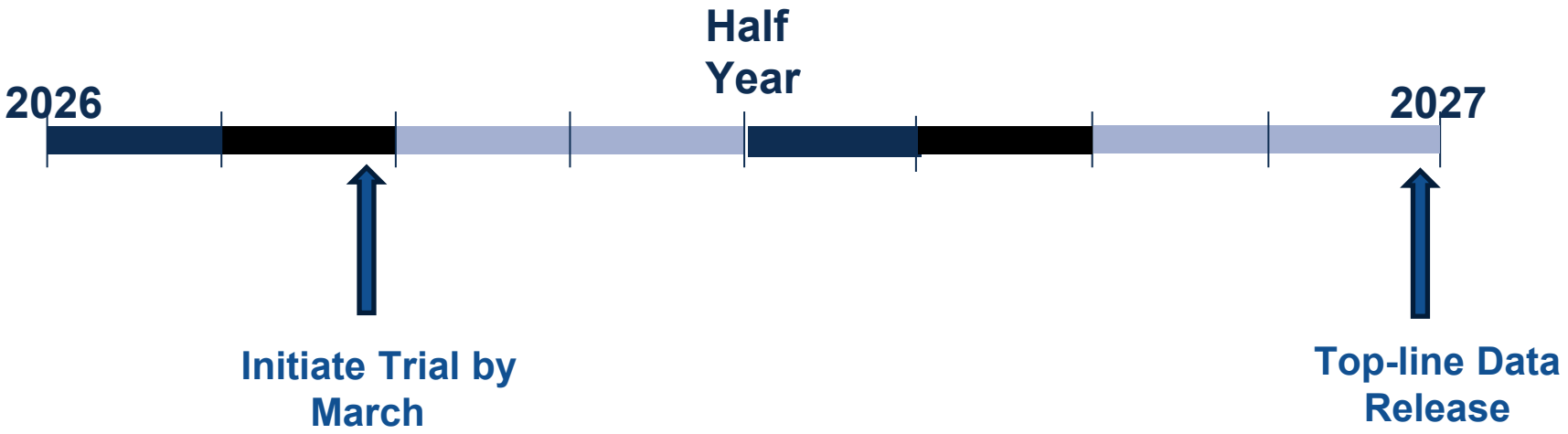
Conduct Meeting with FDA to Discuss Urcosimod's Further Development

- FDA's Expectations for what is an approvable drug to treat NCP.
- No FDA approved drug for this major unmet medical condition.

Proposed Urcosimod Phase 2 Trial to Treat NCP Patients

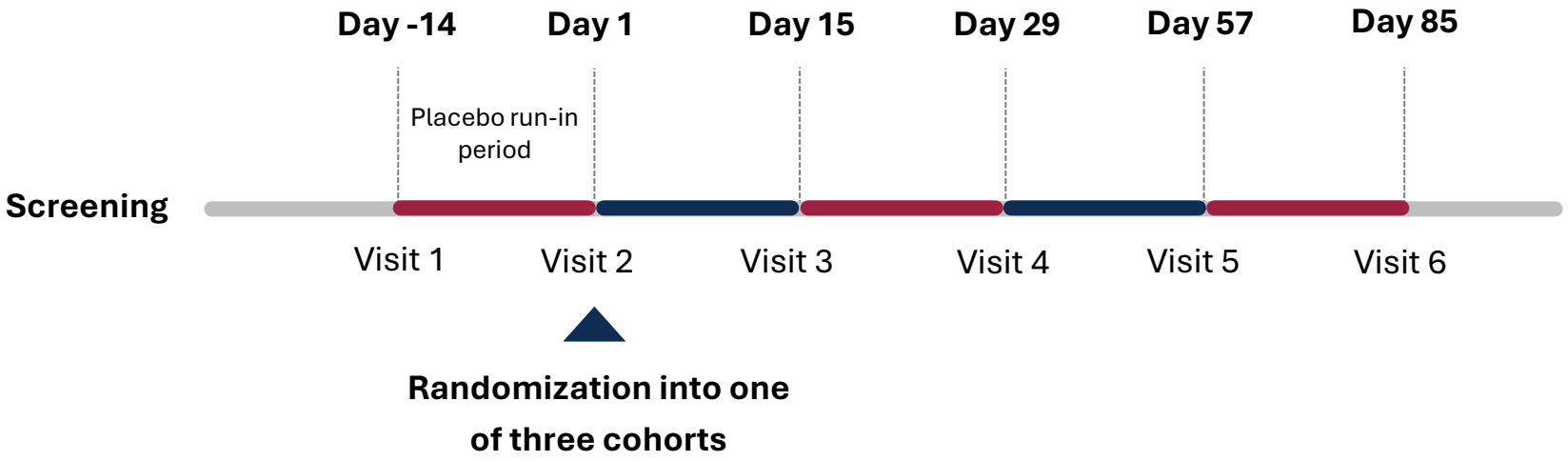
Phase 2, Randomized, Double masked, Placebo-Controlled Study Assessing Safety and Efficacy of Urcosimod in Subjects with NCP

- Number of subjects to be enrolled: ~120 (*calculation by statistician to confirm)
- Number of cohorts: 3 (placebo, 0.025%, 0.05% urcosimod)
- Number of subjects per cohort: 40
- Visits: 5 visits over the course of 16 weeks
- Study duration: 9-12 months
- Clinical Sites: Plan for *at least* 4



Urcosimod DED Phase 2 Trial Design

Note: First Human Trial of Urcosimod



Urcosimod (0.05%) n = 81	Urcosimod (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

CRO Partner: Ora

Patent Protection Through at Least 2039

Urcosimod Intellectual Property:

Composition of Matter: US 10,233,219	**Method of Use (Dry Eye):** US 11,197,906	**Use (Neuropathic Pain):** US 11,254,720
Issued in US to 2034 with potential patent term extension up to 2039	Issued in US to 2037 with potential patent term extension up to 2042	Issued in US to 2034 (+187 days of *PTA)

Key Takeaways

- **Urcosimod** is a novel topical eye drop that targets both ocular pain and inflammation.
- No FDA-approved therapy available for neuropathic corneal pain (NCP).
- Results from **urcosimod** 18-patient Phase 2 “proof-of-concept” trial to treat NCP demonstrated a clear drug effect.
- **Urcosimod,** with recently received fast track designation by FDA, on track for meeting with FDA to provide further advise on its development strategy.
- An FDA approved drug to treat NCP is an undeniable market opportunity for this unmet medical need.
- Experienced leadership team & patent protection until 2039 and beyond.

* Fortune Business Insights, 2024 Report ID FB102413

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