

Addressing Unmet Needs in Corneal and Anterior Segment Diseases

A differentiated therapeutic approach targeting high-value, underserved rare ocular diseases

Corporate Highlights | Q1 2026



Nasdaq: OKYO

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Management Team



Robert J. Dempsey
Chief Executive
Officer/Director

30+ years domestic and global ophthalmic commercial leadership and deep ocular surface experience leading the divestiture of Xiidra® to Novartis in 2019 including \$3.4 billion upfront and up to an additional \$1.9 billion in potential milestone payments and launching Restasis®



Flavio Mantelli, M.D., Ph.D.
Chief Medical
Officer

25+ years domestic and global ophthalmic medical and clinical development leadership focused on cornea and ocular surface diseases, neurotrophic keratopathy, and inflammatory eye conditions; led medical strategy from clinical development to approval for OXERVATE® at Dompé



Gary Jacob, Ph.D.
Chief Development
Officer/Director

35+ years pharmaceutical and biotechnology experience across research and development, operations, business development, and capital financing activities; owns over 30 patents and is the co-inventor of two FDA approved pharmaceutical drugs



Raj Patil, Ph.D.
Chief Scientific
Officer

30+ years of domestic and global ophthalmic experience combining academic scholarship excellence; deep pharmaceutical R&D experience with extensive anterior and posterior segment research experience



Keeren Shah
Chief Financial
Officer

20+ years of finance and accounting leadership across biotech and multiple sectors, spanning operational strategy, capital formation, cash management, regulatory compliance, investor relations, and M&A support

Scientific Advisory Board



Pedram Hamrah, MD



Jay S. Pepose, MD, Ph. D.



Victor Perez, MD



Anat Galor, MD



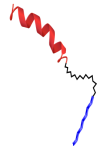
Mark Milner, MD



Mina Massaro-Giordano, MD



Pioneering a New Ocular Therapeutic Market with No Approved Options



Urcosimod (0.05%)
(formally OK-101)

- Novel, non-opioid, preservative-free eye-drop therapy with dual pain-relieving and anti-inflammatory activity for neuropathic corneal pain (NCP)
- Potentially promising candidate for the treatment of both pain and inflammation on the ocular surface



Neuropathic Corneal Pain

- Severe, debilitating condition, significantly under-researched disease with **NO FDA-approved drug**
- Patients commonly experience pain, photophobia, burning and foreign body sensation



Novel MOA

- Urcosimod targets the ChemR23 receptor, a differentiated dual mechanism that modulates both neuropathic pain signaling and immune-mediated inflammation



Clinical Proof of Concept (POC)

- Urcosimod (0.05%) demonstrated **clinically meaningful** pain reduction
 - 5.5-point improvement on a 10-point VAS (vs. ~2.75 for placebo)
 - 75% of patients achieved >80% pain improvement
 - Signaled corneal nerve restoration



Safety

- Favorable safety and tolerability profile, including no serious adverse events



Development Plan

- **Phase 2b/3** NCP trial in ~150 subjects designed to meet pivotal requirements
- Topline data expected 1H2027



FDA Alignment

- **Granted first IND and awarded fast track designation by FDA** for Urcosimod to treat patients with NCP
- Confirmed Phase 2b/3 clinical design, including primary endpoint, sample size and development approach
- Authorized Compassionate Use of Urcosimod for Treatment of Neuropathic Corneal Pain
- Pursuing orphan drug designation strategy



Intellectual Property

- Strong IP protection until 2039

OKYO Development Pipeline





Market Overview

NCP: A Significantly Under-Researched Disease with Substantial Impact on Patient Quality of Life



Disease Background^{1,2,3,4,5,6}

- Neuropathic corneal pain (NCP) is **an ill-defined disease** that causes eyes, face, or head **sensitivity and pain**, often in response to a non-painful stimuli
- Severe, debilitating pain can impact **patient quality of life and ability to work**
- NCP is **challenging to diagnose**, with **diagnosis often by exclusion** and with consideration of history, symptoms, physical examination & imaging findings
- **Misdiagnosis as Dry Eye Disease (DED)** is common due to likeness of symptoms, delaying treatment and relief from pain



NCP is an Underserved Market

- There is presently no FDA-approved drug to treat NCP
- Often underdiagnosed, as the symptoms can overlap with other eye conditions, and treatment can be difficult to manage effectively
- Current treatments are limited to short term NSAIDs, steroids, and opioids in severe cases. Side effects and the risk of addiction to opioids is a serious concern



Symptoms¹

Light / air sensitivity
Foreign body sensation
Burning
Severe eye dryness

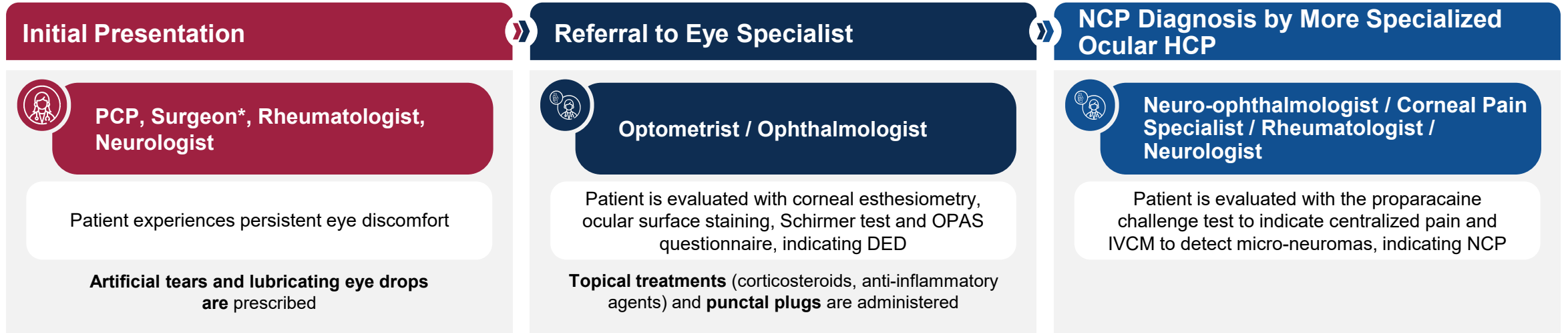


Characteristics of Neuropathic Corneal Pain (NCP)

Definition	Neuropathic pain from corneal nerve dysfunction
Mechanism	Peripheral ± central sensitization
Clinical Signs	Minimal signs despite severe pain
Pain Quality	Burning, electric, stabbing, allodynia
Triggers	Light, wind, touch
Response to Eye Meds	Poor or incomplete response
Diagnosis Type	Specific mechanistic diagnosis
Treatment	Neuromodulators, serum tears, nerve repair
Relationship	Subset of chronic eye pain

(1) American Academy of Ophthalmology. (n.d.). What is neuropathic corneal pain? American Academy of Ophthalmology. Retrieved March 13, 2025, from <https://www.aao.org/eye-health/diseases/what-is-neuropathic-corneal-pain-2>
 (2) Moshirfar M, Benstead EE, Sorrentino PM, et al. Ocular Neuropathic Pain. [Updated 2023 Aug 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK542282/>
 (3) Dieckmann G, Goyal S, Hamrah P. Neuropathic Corneal Pain: Approaches for Management. Ophthalmology. 2017 Nov;124(11S):S34-S47. doi: 10.1016/j.ophtha.2017.08.004. PMID: 29055360; PMCID: PMC5743225.
 (4) Neuropathic/nociplastic ocular pain - symptoms, causes, treatment: Nord. (2025). Retrieved from <https://rarediseases.org/rare-diseases/neuropathic-ocular-pain/>
 (5) Goyal, S., & Hamrah, P. (2016). Understanding neuropathic corneal pain—gaps and current therapeutic approaches. Retrieved from <https://pmc.ncbi.nlm.nih.gov/articles/PMC5607443/>
 (6) Watson, S. L., & Le, D. T.-M. (2024). Corneal neuropathic pain: A review to inform clinical practice. Retrieved from <https://www.nature.com/articles/s41433-024-03060-x>

NCP Patient Journey



Patients are commonly **misdiagnosed** before being referred to more specialized eyecare professional **delaying treatment and worsening symptoms**

Physicians frustrated with lack of **effective diagnostic tools and clear criteria** leading to **delayed diagnosis, underdiagnosis, and misdiagnosis**

Delayed diagnosis results in patients progressing into **centralized pain** which is harder to treat

Rising Scrutiny of Gabapentin Highlights Need for Earlier, Targeted NCP Diagnosis

Wall Street Journal: “The Hidden Risks of America’s Most Popular Prescription Painkiller”

- Gabapentin increasingly prescribed off-label for chronic pain, despite mixed efficacy
- 8 states have reclassified gabapentin schedule V controlled substance; 12 additional states require stricter reporting on use
- Growing concerns around dependence, misuse, and masking underlying disease
- Reliance on systemic pain masking underscores the lack of approved, disease-directed therapies for NCP



December 24, 2025

The background features abstract, overlapping shapes in shades of blue and maroon. A light blue shape is on the left, overlapping a darker blue shape, which in turn overlaps a large maroon shape that dominates the bottom and right portions of the slide.

Mechanism of Action & Clinical Rationale

Urcosimod: A Lipid-Conjugated Chemerin Peptide

- **First-in-Class chemerin receptor agonist** that modulates neuro-immune cross-talk
- **Dual mechanism of action:** targets both immune cell-mediated inflammation and neuronal/glia cell populations in the dorsal root ganglion
- **Topically active peptide** designed for enhanced potency and corneal retention
- **Preservative-free, EDTA-free, and isotonic formulation**, optimized for sensitive eyes and chronic use

Targeting ChemR23

(CMKLR1 GPCR Receptor)

Modulates

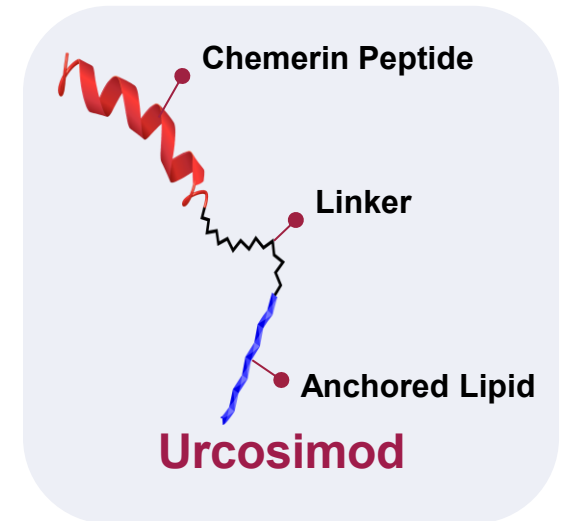
Inflammation pain

Receptor localization

Expressed on immune and neuronal cells, linking inflammation and pain signaling

Endogenous ligand

Chemerin: 136 aa peptide



Urcosimod Phase 2 DED Trial

Phase 2 Randomized, Placebo-Controlled DED Trial

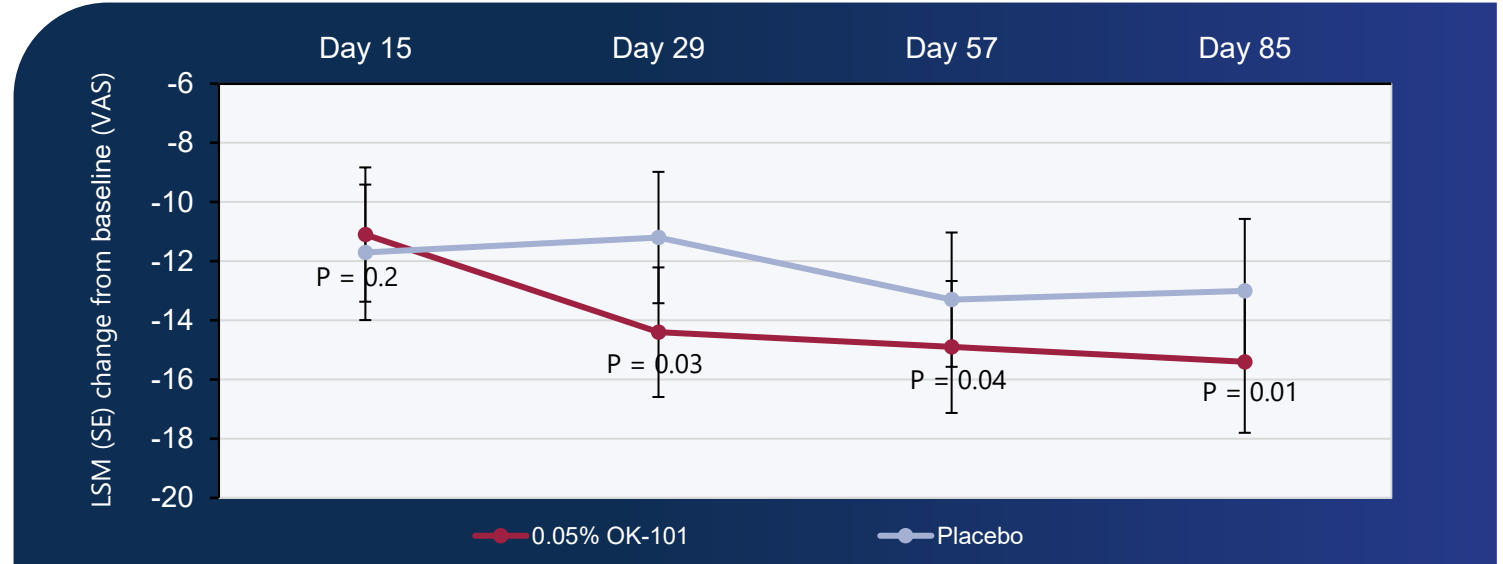
- **Enrollment:** 240 randomized subjects / ~80 per study arm
- **Treatment arms:** 3 (Placebo, OK-101 0.05%, OK-101 0.1%)
- **Study duration:** 85 days (~12 weeks) with 6 scheduled patient visits
- **Clinical sites:** Multicenter (U.S.)

Endpoints

- **Primary (through Day 85):** Inferior Corneal Staining (sign); Ocular Discomfort Score (symptom)
- **Secondary:** Total Conjunctival Staining (sign), Tear Film Break-up Time (TFBUT) (sign), Blurred Vision, Pain, Burning/Stinging, Daily Symptom Diary

Urcosimod Demonstrated Significant Pain Relief in Phase 2 DED Trial

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



No Severe Adverse Events Demonstrated in Phase 2 DED Study (240 Subjects)

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)

Urcosimod Drop Comfort: 2 Minutes Post-Instillation Study Eye

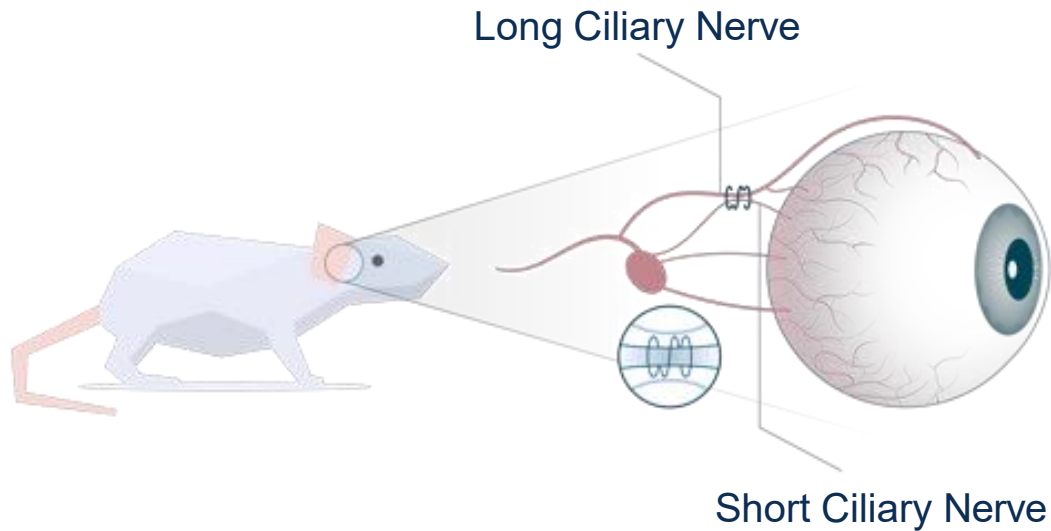
Drop Comfort	Urcosimod (0.1%) (n=79)	Urcosimod (0.05%) (n=77)	Placebo (n=76)
Mean Score (SD)	2.5 (2.32)	2.3 (2.32)	1.8 (1.73)
Median	2.0	1.0	1.5

Significant Pain Relief Efficacy and Safety Profile Supported Strong Evidence for Clinical Development Rationale in NCP

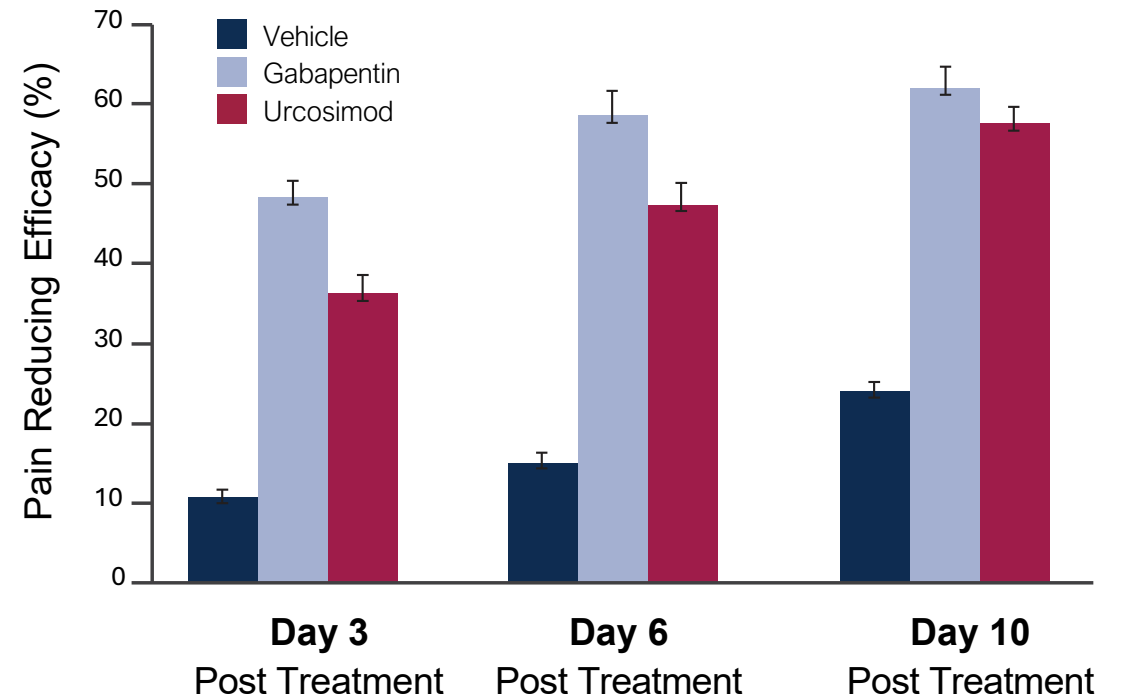
Abbreviations: AE = Adverse Event; TEAE = Treatment-Emergent Adverse Event; SAE = Serious Adverse Event; TE-SAE = Treatment-Emergent Serious Adverse Event.

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



Urcosimod: NCP Clinical Development Plan

Urcosimod Phase 2a NCP Trial Design

ENDPOINTS

Primary Endpoint

(through 12 weeks)

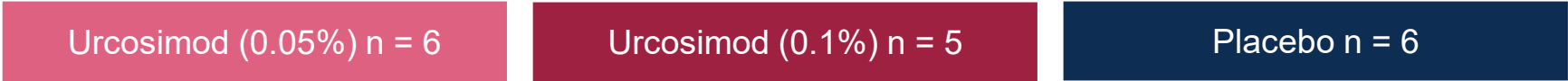
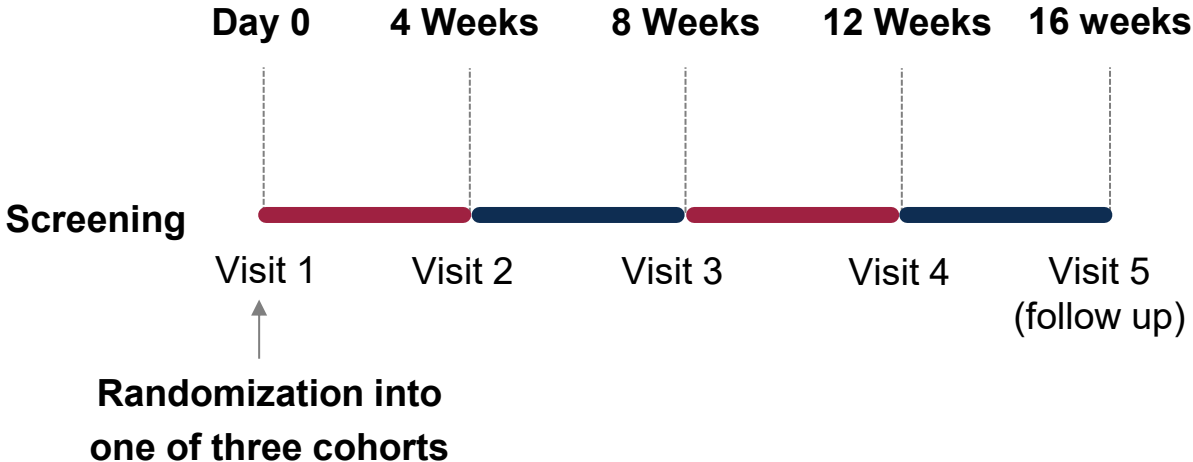
Pain (Visual Analog Scale)

Secondary Endpoint

Ocular Pain by OPAS scores
 QoL improvement by OPAS
 Drop comfort

Exploratory Endpoints

Change in corneal sensation
 Change in corneal nerve density and length
 Presence or absence of microneuromas



Study Overview

Total Subjects: Enrolled = 18
 Screen Failures = 6
 Randomized Subjects = 18

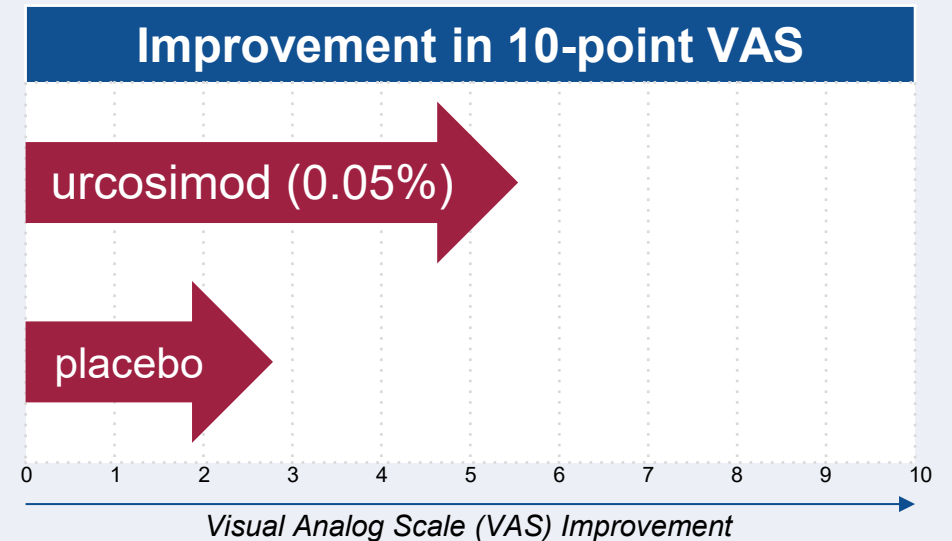
Baseline characteristics were balanced amongst treatment groups
No drug-related SAEs, most AEs were mild stinging & burning
 1 discontinuation due to medical reason unrelated to drug in 0.1% urcosimod group

Phase 2a NCP Clinical Trial Demonstrated Promising Drug Effect

Phase 2a, Randomized, Double Masked, Placebo-Controlled Study Assessing Safety and Efficacy for Urcosimod in Subjects with NCP

STUDY RESULTS

- After 12 weeks of treatment, 75% of per-protocol patients receiving urcosimod (0.05%) showed greater than 80% reduction in neuropathic corneal pain, as measured by VAS, demonstrating highly effective treatment
- Urcosimod (0.05%) demonstrated a mean change from baseline in pain scores as early as Week 4, with sustained efficacy maintained throughout the trial
- Notably, all these responders entered the study with moderate to severe NCP pain scores despite prior use of maximum medical therapy



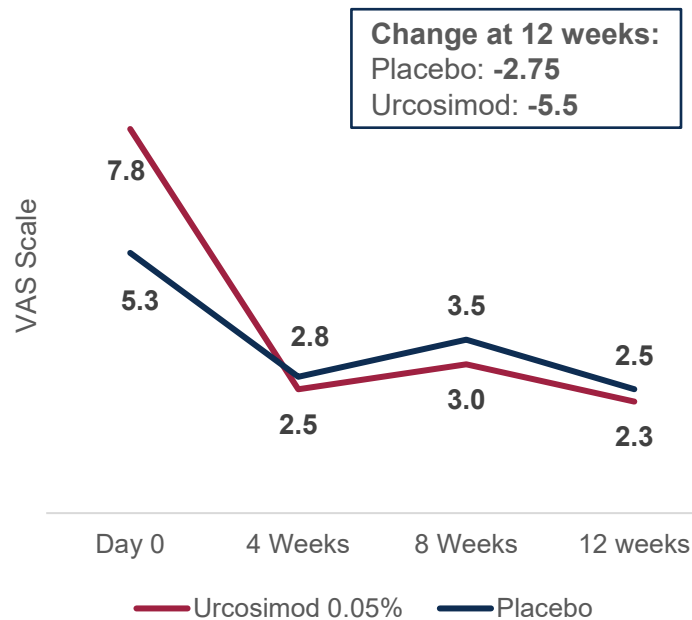
Urcosimod (0.05%) group showed a mean pain score improvement of **5.5 points** on a 10-point VAS, compared with a mean improvement of 2.75 points for placebo

Pain Scores Across 12 Weeks (VAS Scale; Urcosimod 0.05% vs Placebo)

- Higher baseline pain severity was associated with a greater treatment effect of urcosimod versus placebo
- Steep decline of pain in just 4 weeks
- For the Phase 2b/3 study, enrollment is expected to be enriched with moderate to severe patients (VAS scores >5), with the intention of optimizing the probability to detect drug effect

Per-Protocol Group

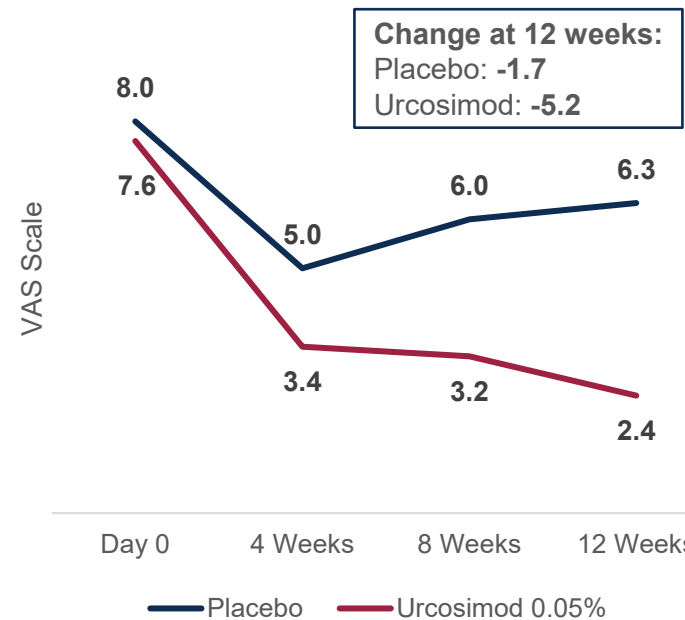
Mean VAS Scores



Placebo n = 4; Urcosimod n = 4

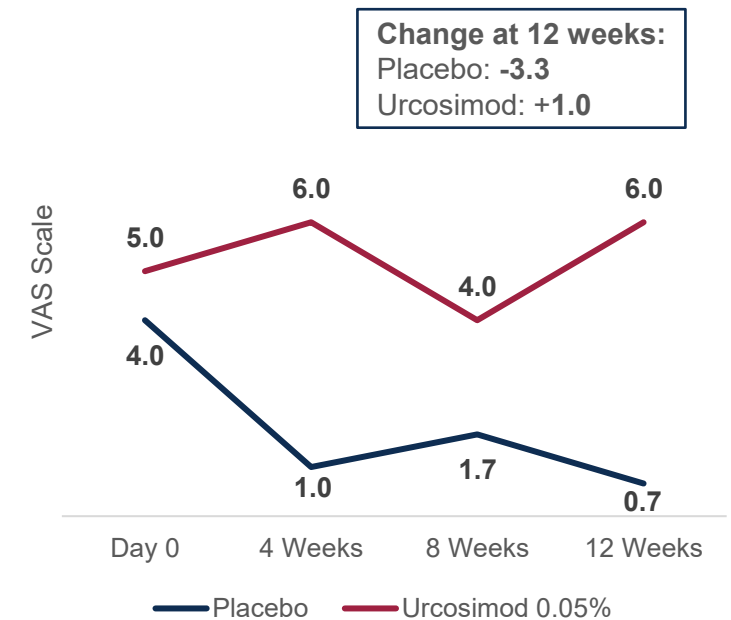
Intent-To Treat Group

Moderate-to-Severe Pain Group
(VAS > 5 at baseline)



Placebo n = 3; Urcosimod n = 5

Mild-to-Moderate Pain Group
(VAS ≤ 5 at baseline)



Placebo n = 3; Urcosimod n = 1

Urcosimod (0.05%) Signals Promising Nerve Growth Potential

Favorable impact of urcosimod (0.05%) on corneal nerve health, demonstrating corneal nerve restoration

- Median increases in total nerve fiber count vs. placebo
 - (+2.0, n/0.16 mm², IQR 0.54 to 3.63) vs. placebo (−1.92, n/0.16 mm², IQR −2.79 to −0.04)
- Median increases in total nerve fiber length vs. placebo
 - (+2.6 mm/mm², IQR 1.55 to 5.67; p = 0.057) vs. placebo (−1.63 mm/mm², IQR −3.76 to 0.63)

Consistent anatomical improvements support **corneal nerve restoration** and **first-in-class** potential

All values represent median (n = 4)

FDA Endorsed Urcosimod Phase 2b/3 NCP Trial

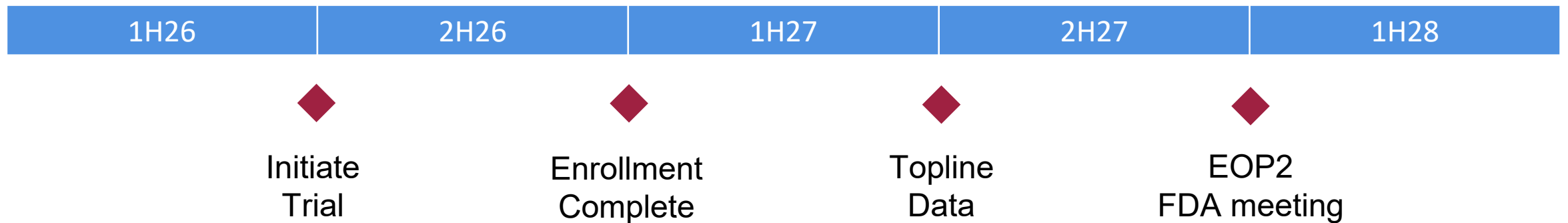
Phase 2b/3 Randomized, Double-Masked, Placebo-Controlled Study of Urcosimod in NCP

- **Planned enrollment:** ~150 subjects
- **Treatment arms:** 3 (Placebo, Urcosimod 0.025%, Urcosimod 0.05%)
- **Subjects per arm:** 50
- **Treatment duration:** 12 weeks
- **Visits:** 5 scheduled visits
- **Clinical sites:** 6-8 centers

FDA confirmed:

- Primary endpoint of the Visual Analogue Scale (VAS) pain reduction
- ≥ 2 -point improvement on the VAS scale represents a meaningful treatment effect

Value Inflection Points



Neuropathic Corneal Pain (NCP) Development Plan

2024

- IND Cleared by FDA for OK-101 to Treat NCP
- Phase 2a Randomized, Placebo-Controlled 48-Patient Trial Initiated to treat NCP

2025

- Closed Trial to Accelerate Clinical Development
- Phase 2a Favorable NCP Topline Readout
- FDA grants Fast Track Designation for NCP

2026+

- FDA Type C Meeting
- Initiate Phase 2b/3 Multiple-Dose Study
- Complete enrollment in Phase 2b/3 (~150 subjects)
- Phase 2b/3 topline data readout

Urcosimod Patent Protection Through at Least 2039

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 Patent Term Extension)

Key provisional patent filed covering micellar physico-chemical properties of urcosimod.

Potential exclusivity to 2047

Rare Corneal Disease*

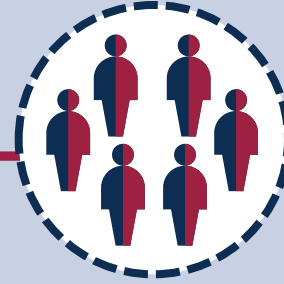
Provisional patent filing governing additional ocular disease target matching drug's MOA

Fast-Tracking a Potential Therapy for NCP Patients with High Unmet Needs



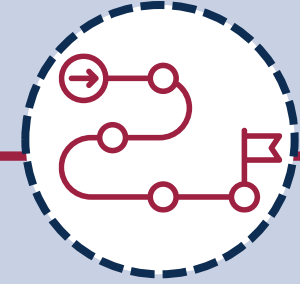
CLINICAL EVIDENCE

- Phase 2a Proof of Concept trial to treat NCP clearly demonstrated a promising drug effect
- 5.5-point improvement on a 10-point VAS
- 75% of treated patients achieved >80% pain improvement



UNMET NEED

- No FDA-approved treatment available for neuropathic corneal pain (NCP)
- Opportunity for first in class first line therapy with positive reimbursement



NEAR TERM MILESTONES

- FDA confirmed alignment on development strategy
- Initiate Phase 2b/3 trial (2Q26)
- Phase 2b/3 trial fully enrolled (4Q26)
- Topline data (1H27)