



(NASDAQ: OCUL)

# OTX-TIC, AN INTRACAMERAL HYDROGEL-BASED TRAVOPROST IMPLANT TO TREAT PATIENTS WITH GLAUCOMA & OCULAR HYPERTENSION

## PHASE 1 TRIAL RESULTS

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GLAUCOMA 360 | SAN FRANCISCO, CA | FEBRUARY 11, 2022

*Ocular*  
Therapeutix™

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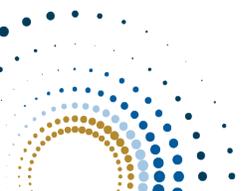
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## **Financial Disclosures:**

- Dr. Goldstein is an employee of Ocular Therapeutix, Inc.

## **Study Disclosures:**

- The presentation discusses an investigational product, OTX-TIC. Its efficacy and safety profile has not been established and it has not been approved by the FDA
- Funding was provided by Ocular Therapeutix, Inc. for the study



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# PIPELINE AT A GLANCE

PRODUCT/PROGRAM	THERAPEUTIC FOCUS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY APPROVAL
<b>RETINA</b>						
<b>OTX-TKI</b> (axitinib intravitreal implant)	Wet AMD, DME and RVO*	▶				
<b>GLAUCOMA</b>						
<b>OTX-TIC</b> (travoprost intracameral implant)	Glaucoma and ocular hypertension	▶				
<b>OCULAR SURFACE DISEASES</b>						
<b>OTX-CSI</b> (cyclosporine intracanalicular insert)	Dry eye disease	▶				
<b>OTX-DED</b> (dexamethasone intracanalicular insert)	Episodic dry eye disease	▶				
<b>Dextenza®</b> (dexamethasone ophthalmic insert) 0.4mg	Ocular itching associated with allergic conjunctivitis	▶				◊
<b>SURGICAL</b>						
<b>Dextenza®</b> (dexamethasone ophthalmic insert) 0.4mg	Postsurgical ocular inflammation and pain	▶				◊
<b>ReSure®</b> SEALANT	Cataract incision sealant	▶				◊

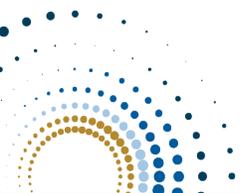
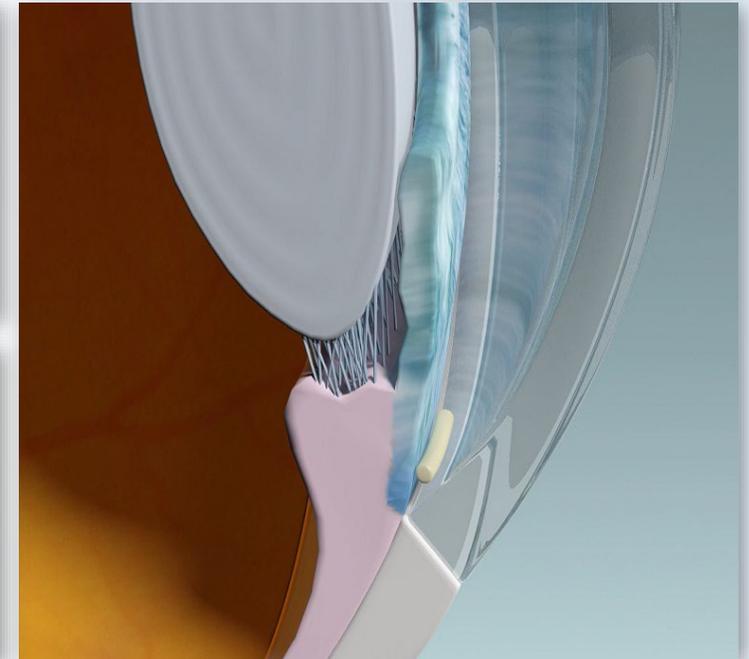
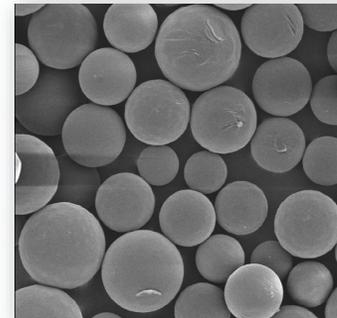
\*Wet Age-related Macular Degeneration (Wet AMD), Diabetic Macular Edema (DME), Retinal Vein Occlusion (RVO)

DEXTENZA [package insert]. Bedford, MA: Ocular Therapeutix Inc; 2021 <https://www.dextenza.com/wp-content/uploads/DEXTENZA-Full-Prescribing-Information.pdf>  
 ReSure Sealant. Instructions for Use. LCN 80-1004-011 Rev C. Ocular Therapeutix, Inc., Bedford, MA. <https://www.resuresealant.com/wp-content/uploads/2021/03/LCN-80-1004-011-Rev-C-ReSure-Sealant-Instructions-for-Use.pdf>

# DRUG DELIVERY TO THE INTRACAMERAL SPACE

## Factors for Consideration in Designing a Long Duration Intracameral Implant:

- ❑ Clinically-meaningful decrease in IOP  
*Well-tolerated with clinically-meaningful efficacy*
- ❑ Duration of therapy  
*4 months or more*
- ❑ Bioresorbable  
*Duration of drug and duration of carrier vehicle*
- ❑ Implant location and movement  
*Limited movement and cosmetically invisible, but able to be monitored*
- ❑ Corneal health  
*Gentle to the endothelium*



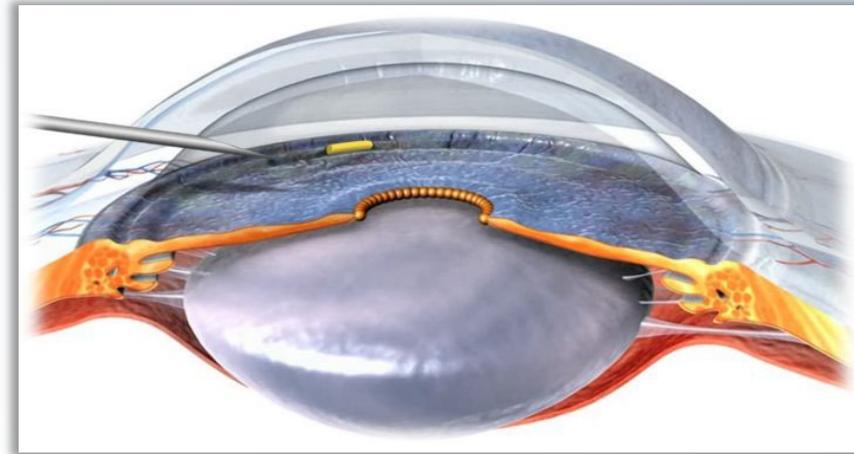
# OTX-TIC (TRAVOPROST IMPLANT) FOR INTRACAMERAL INJECTION

## Polyethylene glycol (PEG)-based Hydrogel Platform

- **Completely biodegrades** via ester hydrolysis
- **Biocompatible** with low potential for inflammation

## Travoprost (Active Ingredient)

- Encapsulated in microparticles for controlled and sustained delivery over months



## OTX-TIC, a novel hydrogel-based, biodegradable, sustained-release travoprost implant

- Goal of delivering travoprost for 4-6 months with a single implant
- Preservative-free
- Hands-free alternative to traditional chronic eye drop therapy
- Administered via a single injection with proprietary injector (26G-27G)
- Fully biodegradable

# OTX-TIC PHASE 1 STUDY DESIGN

## DESIGN

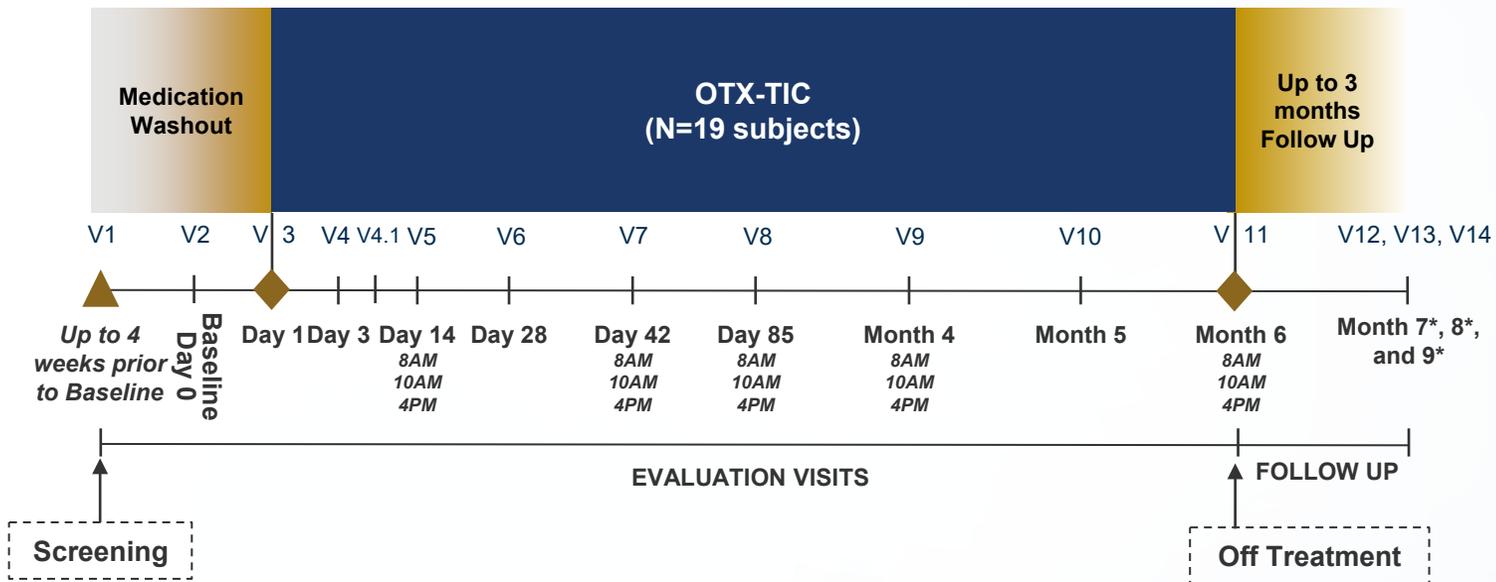
- Open-label, proof-of-concept study
- US study, 19 subjects at 5 sites
- One eye per patient will be treated
- Key Inclusion criteria:
  - Controlled ocular HTN or POAG
  - Open, normal anterior chamber angles on gonioscopy

## EVALUATIONS

- Safety, tolerability, and biological activity
- Diurnal IOP at Baseline, 2 weeks, 6 weeks, 12 weeks, Month 4, and Month 6 (8 AM, 10 AM, 4 PM)

## ACTIVE COMPARATOR

- Non-study eye receives **topical travoprost** daily



	OTX-TIC Dose
Cohort 1 (n=5)	15 µg
Cohort 2 (n=4)	26 µg
Cohort 3 (n=5)	15 µg (fast-degrading hydrogel)
Cohort 4 (n=5)	5 µg (fast-degrading hydrogel)

\* Monthly visits until IOP is within 10% of baseline or until clinically stable

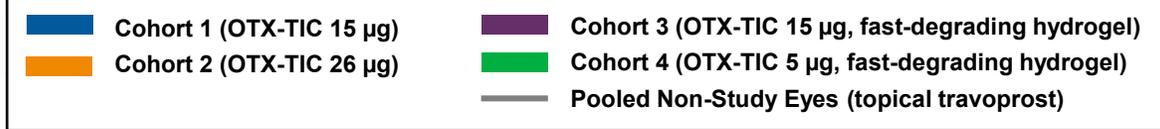
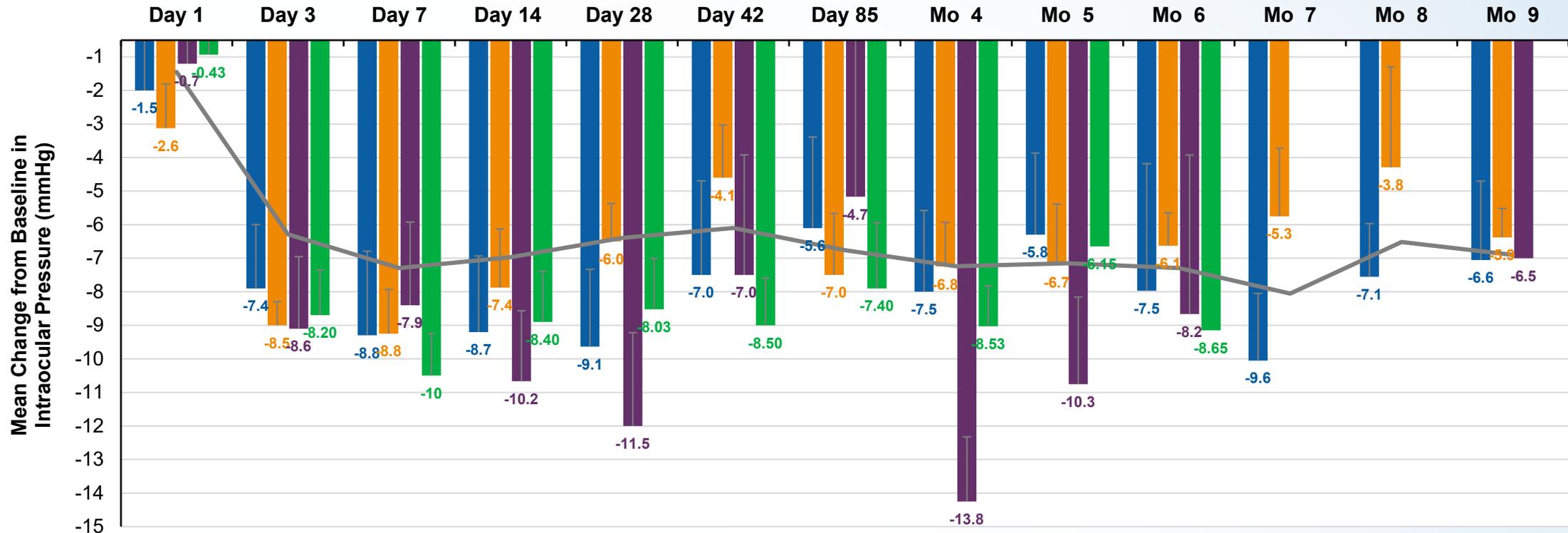
# BASELINE DEMOGRAPHICS

	Cohort 1 (n=5)	Cohort 2 (n=4)	Cohort 3 (n=5)	Cohort 4 (n=5)	All Subjects (N=19)
<b>Mean age (SD), years</b>	72.8 (5.6)	74.3 (7.1)	65.8 (7.9)	66.0 (14.4)	69.5 (10.2)
Range	65-80	63-82	53-76	47-84	47-84
<b>Female, n (%)</b>	3 (60%)	4 (100%)	4 (80%)	4 (80%)	15 (78.9%)
<b>Race, n (%)</b>					
White	5 (100%)	2 (50%)	2 (40%)	5 (100%)	14 (73.4%)
Black	0	2 (50%)	3 (60%)	0	5 (26.3%)
<b>Mean Baseline IOP (SD) After Washout, mmHg</b>					
Study eye (OTX-TIC)	26.8 (3.5)	26.1 (0.9)	26.5 (4.3)	24.9 (0.8)	26.1 (2.8)
Non-study eye (Topical travoprost)	25.8 (2.5)	25.1 (0.9)	25.2 (4.0)	22.9 (1.9)	24.7 (2.7)
<b>IOP Lowering Medications Prior to Washout, n (%)</b>					
Naïve	1 (20%)	0	0	3 (60%)	4 (21%)
1 Medication	2 (40%)	3 (75%)	5 (100%)	2 (40%)	12 (63%)
2 Medications	1 (20%)	1 (25%)	0	0	2 (11%)
≥3 Medications	1 (20%)	0	0	0	1 (5%)

NOTE: unmonitored data

# CHANGE FROM BASELINE IOP

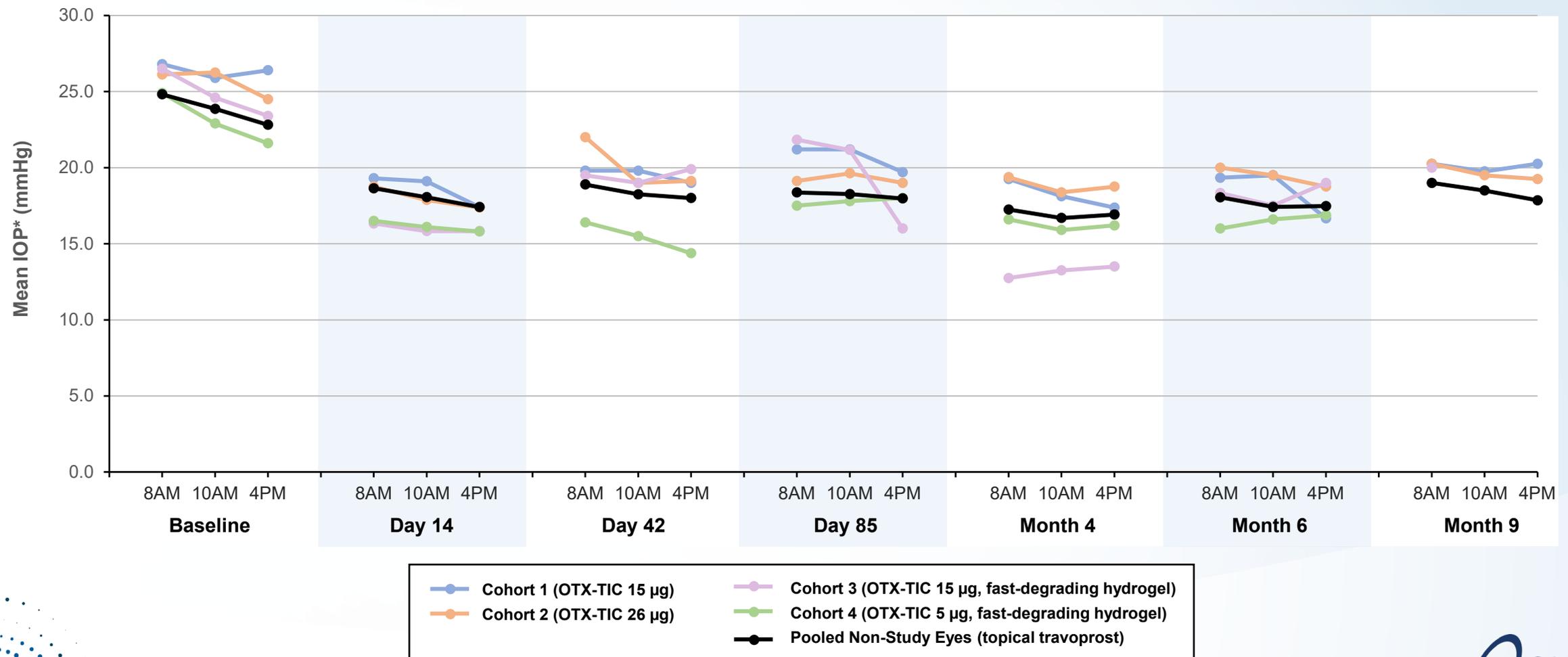
**IOP Reduction Began 2 Days Following Implantation of OTX-TIC and was Comparable to Topical Travoprost**



NOTE: unmonitored data

# DIURNAL IOP

**OTX-TIC Reduced IOP Similarly to Topical Travoprost Throughout the 6 Month Study Period**



\* Subjects who received rescue therapy (ie, IOP lowering medication other than OTX-TIC) were excluded from analysis  
 NOTE: unmonitored data

# DURATION OF EFFECT

**Cohort 2 Showed the Most Consistent Durable Response in All Subjects Up to Month 6 & 50% of Subjects Up to Month 9**

**Percentage of Study Eyes Not Requiring Rescue Therapy After a Single Implant Administration**

	Day 42 % (n/N)	Day 85 % (n/N)	Month 4 % (n/N)	Month 5 % (n/N)	Month 6 % (n/N)	Month 7 % (n/N)	Month 8 % (n/N)	Month 9 % (n/N)	Month 10-22 % (n/N)
<b>Cohort 1 (15 µg) N=5</b>	100% (5/5)	100% (5/5)	80% (4/5)	80% (4/5)	60% (3/5)	40% (2/5)	40% (2/5)	40% (2/4)	20 (1/5)
<b>Cohort 2 (26 µg) N=4</b>	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	75% (3/4)	50% (2/4)	NA
<b>Cohort 3 (15 µg) (Fast-degrading) N=5</b>	100% (5/5)	60% (3/5)	40% (2/5)	40% (2/5)	40% (2/5)	20% (1/5)	20% (1/5)	20% (1/5)	NA
<b>Cohort 4 (5 µg) (Fast-degrading) N=5</b>	100% (5/5)	100% (5/5)	80% (4/5)	80% (4/5)	80% (4/5)	NA	NA	NA	NA
<b>All Cohorts N=19</b>	100% (19/19)	89% (17/19)	74% (14/19)	74% (14/19)	68% (13/19)	50% (7/14)	43% (6/14)	39% (5/13)	20% (1/5)



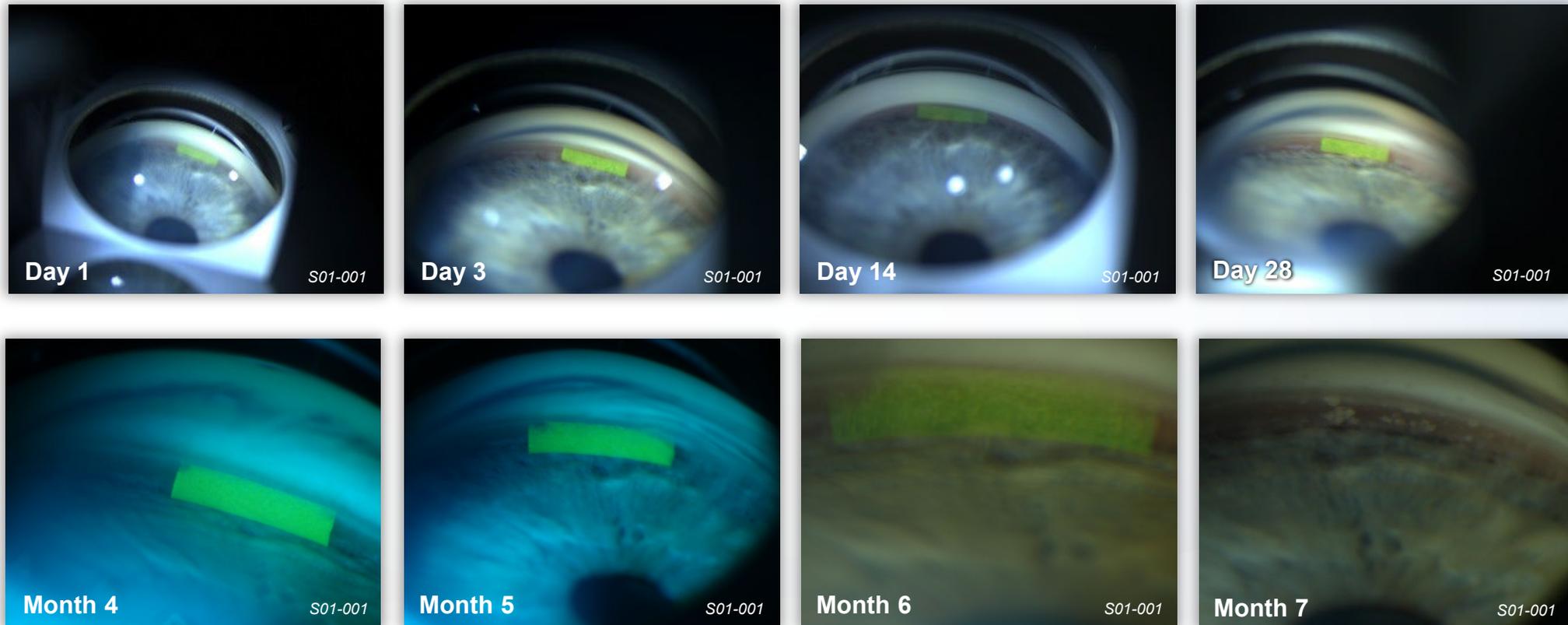
NOTE: unmonitored data

# IMPLANT VISUALIZATION

**Implant Movement:** No noticeable movement observed

## Biodegradation

- **Cohorts 1 & 2:** Implant biodegraded by 5-7 Months
- **Cohorts 3 & 4:** Fast-degrading implants biodegraded by 3-5 months in majority of subjects



# SAFETY OVERVIEW

*OTX-TIC was generally well tolerated with a favorable safety profile*

## Ocular Adverse Events in the Study Eye

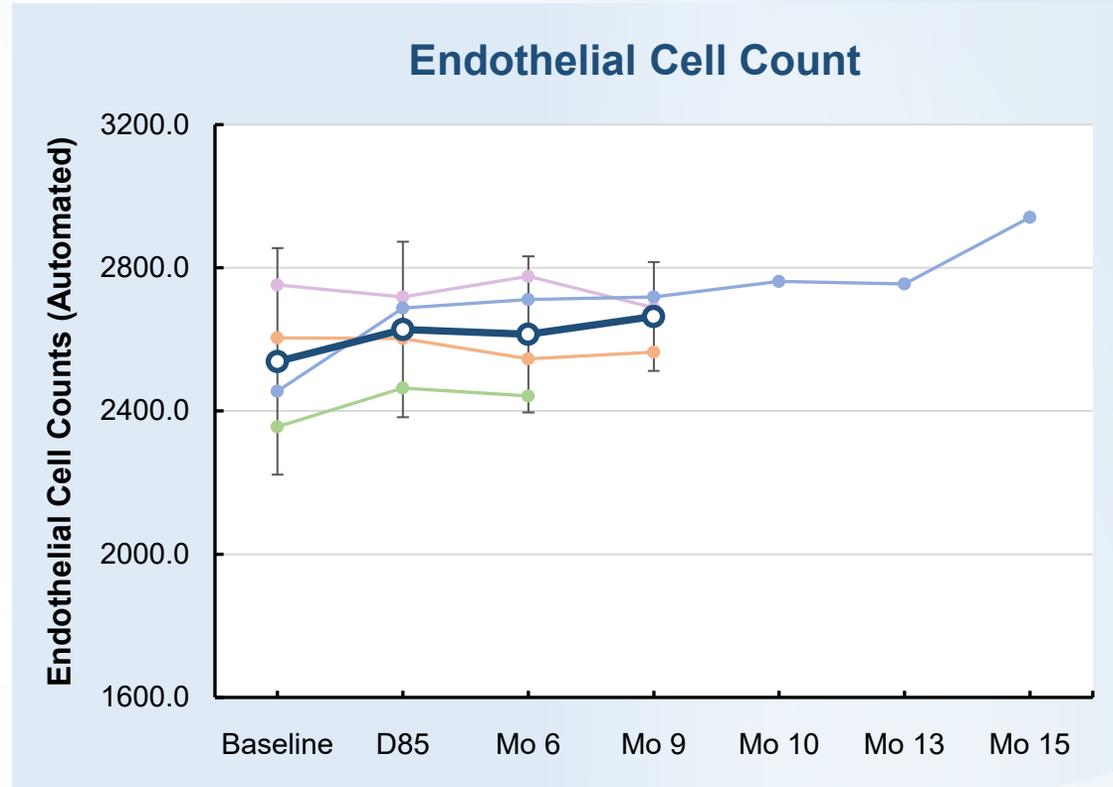
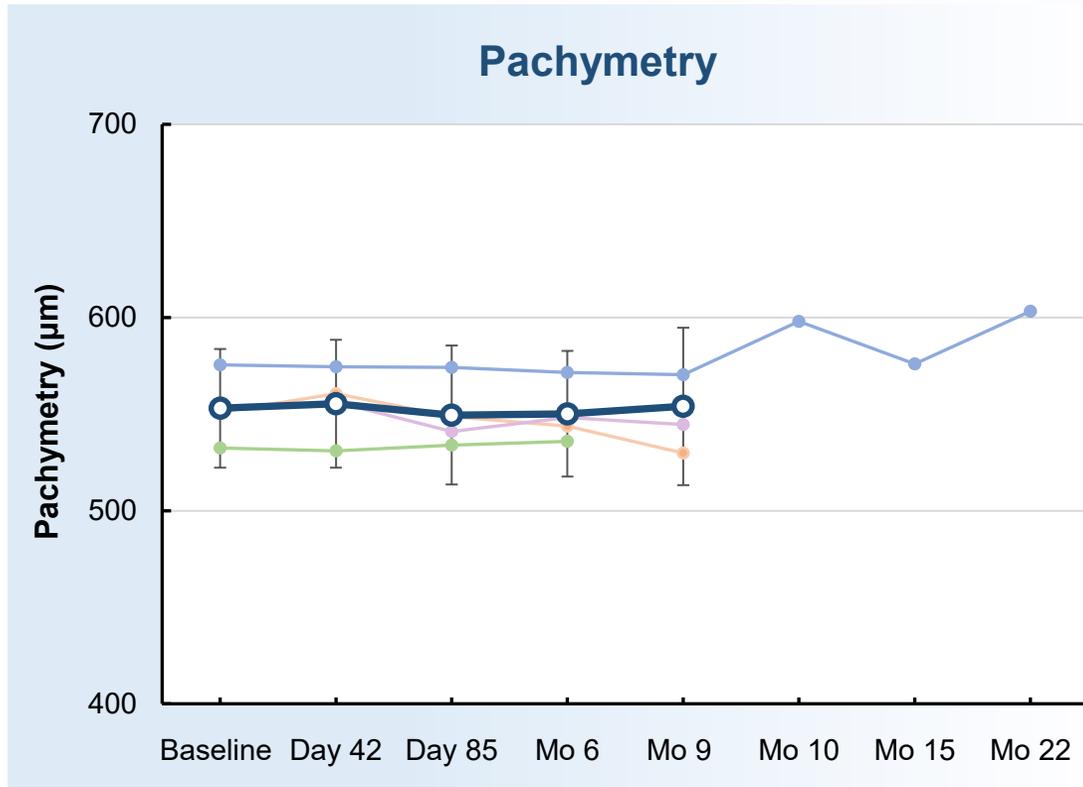
Ocular Adverse Event Term, n	Fast-degrading Hydrogel				All Cohorts N=19
	Cohort 1 (15 µg) N=5	Cohort 2 (26 µg) N=4	Cohort 3 (15 µg) N=5	Cohort 4 (5 µg) N=5	
Iritis	2	2	1	1	6
Peripheral anterior synechiae	3	0	0	0	3
Corneal edema	0	1	2	0	3
Elevated IOP	0	0	3	0	3
Transient BCVA decrease	0	1	1	0	2
Subconjunctival hemorrhage	0	0	1	0	1
Posterior vitreous detachment	1	0	0	0	1
Inferior corneal keratic precipitates	0	1	0	0	1
<b>Total AEs</b>	<b>6</b>	<b>5</b>	<b>8</b>	<b>1</b>	<b>20</b>

In Cohort 1, two same subjects had iritis and peripheral anterior synechiae.

NOTE: unmonitored data

# CORNEAL HEALTH

*Pachymetry and Endothelial Cell Counts Indicate No Clinically-Meaningful Change from Baseline*



- All Cohorts
- Cohort 1 (OTX-TIC 15 µg)
- Cohort 2 (OTX-TIC 26 µg)
- Cohort 3 (OTX-TIC 15 µg, fast-degrading hydrogel)
- Cohort 4 (OTX-TIC 5 µg, fast-degrading hydrogel)

Error bars represent standard deviations for all study eyes data.  
NOTE: unmonitored data

# CONCLUSIONS

## *OTX-TIC shows potential as a durable, sustained-release glaucoma therapy*

- Clinically-meaningful decrease in IOP**  
OTX-TIC produced IOP lowering effects comparable to travoprost therapy as early as two days following administration
- Duration of therapy**  
Many subjects exhibited duration of IOP-lowering effect of 6+ months in Cohorts 1 and 2, and between 3-6 months in Cohorts 3 and 4 (fast degrading implant) with a single implant: Longest and most consistent IOP lowering in Cohort 2
- Bioresorbable**  
Implant biodegraded in 5-7 months (Cohorts 1 & 2); Fast degrading implants biodegraded in 3-5 months (Cohorts 3 & 4)
- Implant location and movement**  
Implant was not observed to move at slit lamp and was visible at all exams in all patients using gonioscopy
- Corneal health**  
Endothelial cell counts, pachymetry assessments, and slit lamp examinations indicate no changes from baseline

**NEXT STEPS: Phase 2 Trial in Q1 2022**

NOTE: unmonitored data

# OTX-TIC PHASE 2 STUDY

## DESIGN

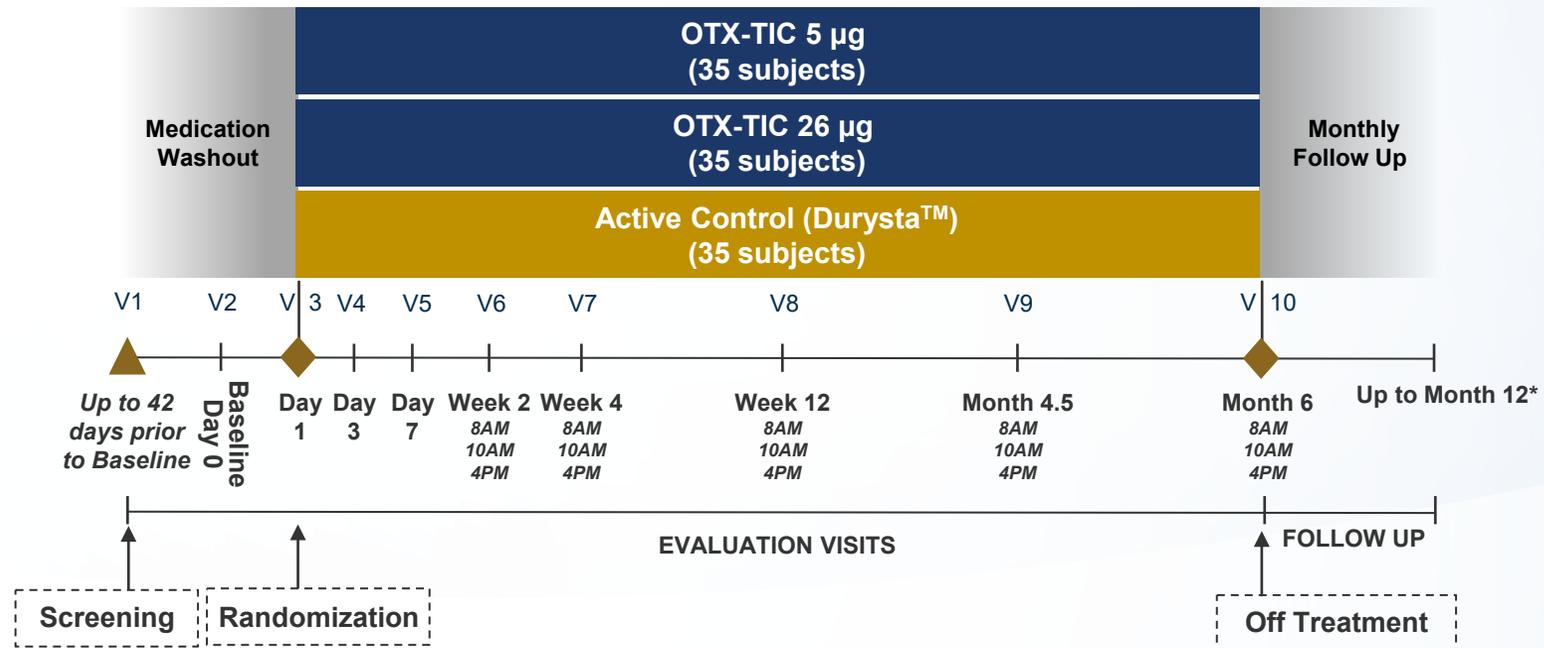
- Prospective, multi-center, randomized, parallel-group, controlled study
- Approximately 105 subjects at 15-20 US sites
- 35 subjects per arm, 3 arms; Randomization 1:1:1
- Key Inclusion criteria:
  - Controlled ocular HTN or POAG
  - Open, normal anterior chamber angles on gonioscopy

## OBJECTIVES

- Safety, tolerability, and efficacy
- Diurnal IOP changes from baseline (8AM, 10AM, 4PM) at 2, 6, and 12 weeks

## ACTIVE COMPARATOR

- Control arm eye receives one injection of Durysta™
- Non-study eye receives topical PGA daily



\* Monthly visits until IOP is within 10% of baseline for up to 6 months, if needed

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TRANSFORMING  
DRUG DELIVERY  
LEVERAGING A NOVEL  
TECHNOLOGY PLATFORM

THANK YOU