

Phase 3 Trial of OTX-TKI (SOL-1) for Wet AMD

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Disclosures and Disclaimers

Financial Disclosures

- **Consultant:** Akebia, Alexion, Aspire, Boehringer Ingelheim, Feliqs, GigCapital7, **Ocular Therapeutix**, Plenoptika, Vision Labs AI
- **Stockholder:** Ainsly Limited, dSenz, Feliqs, **Ocular Therapeutix**, Osanni Bio, Pr3vent, Plenoptika, Pykus, RetinaBio, Vision Labs AI

Presentation Disclaimer

- The following presentation discusses OTX-TKI - an investigational product candidate that has not been approved by the FDA or any other regulatory body; safety and effectiveness have not been established

How Far Have We Extended Treatment?

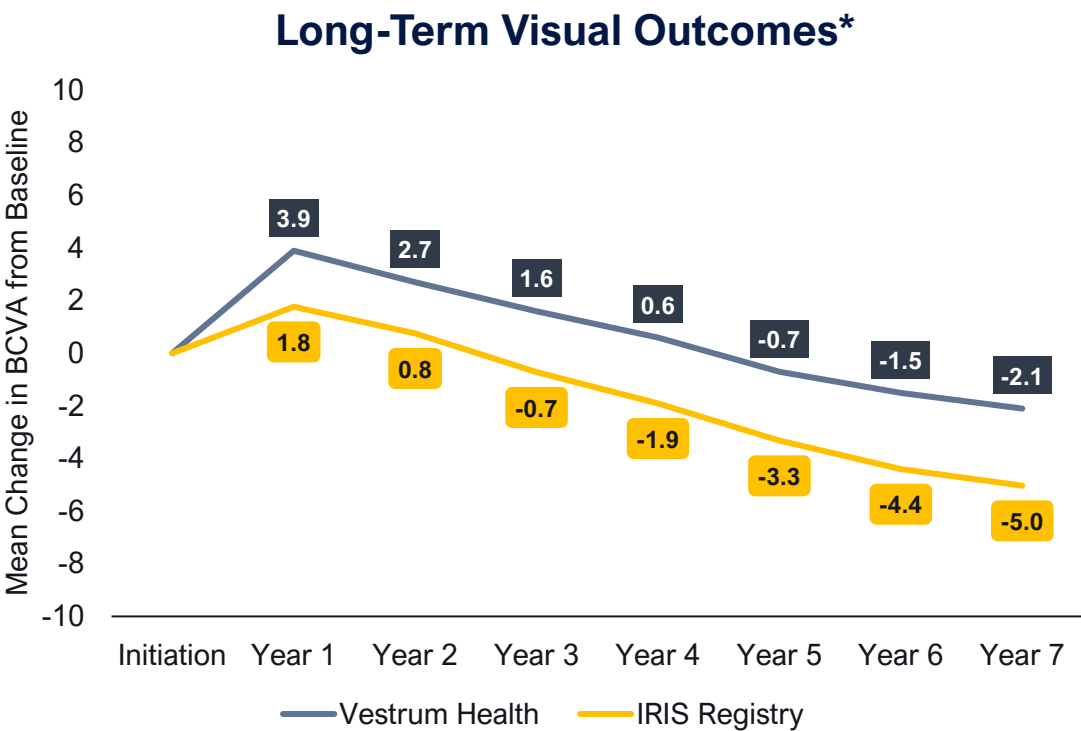
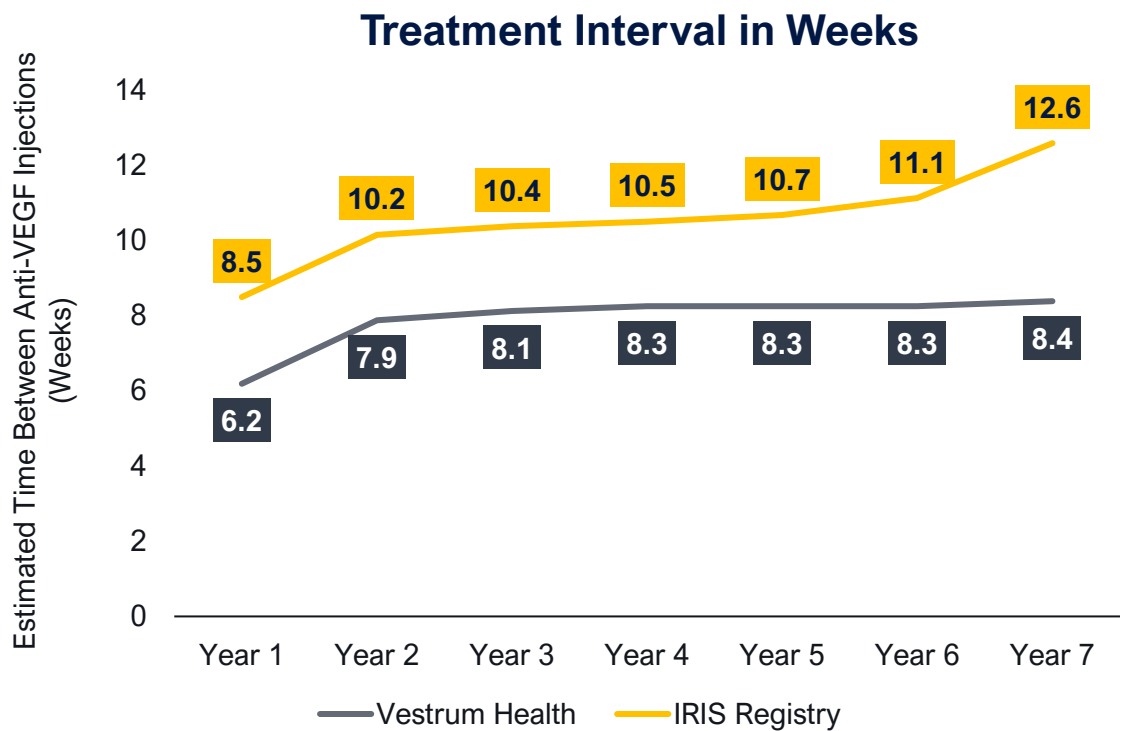
DRUG / TRIAL	INTERVAL STUDIED	% ACHIEVING INTERVAL	TRIAL TYPE
Ranibizumab 0.5 mg MARINA / ANCHOR ^{1,2}	Every 4 weeks	FIXED REGIMEN	SUPERIORITY
Aflibercept 2 mg VIEW1 / VIEW2 ³	Every 4-8 weeks	FIXED REGIMEN	Non-inferiority
Brolucizumab 6 mg HAWK / HARRIER ⁴	Up to 12 weeks	~56%	Non-inferiority
Faricimab TENAYA / LUCERNE ⁵	Up to 16 weeks	~46%	Non-inferiority
Aflibercept 8 mg PULSAR ⁶	Up to 16 weeks	~77%	Non-inferiority
Ranibizumab Port Delivery System ARCHWAY ⁷	Every 24 weeks	~98%	Non-inferiority
OTX-TKI SOL-1	36 weeks 52 weeks	~75% supplemental-free ~69% supplemental-free	SUPERIORITY

The data presented here include a comparison of results from distinct clinical trials. These studies featured varying inclusion and exclusion criteria, baseline characteristics, and patient demographics which may significantly impact clinical outcomes. Because comparisons between these trials may not be generalizable, this overview is for informational purposes only and does not constitute a head-to-head evaluation or definitive proof of relative therapeutic value.

SOL-1: Supplemental-free subjects include those who did not require rescue injections as specified by the protocol.
1. Rosenfeld PJ, et al. *N Engl J Med*. 2006;355(14):1419–1431. 2. Brown DM, et al. *N Engl J Med*. 2006;355(14):1432–1444. 3. Heier JS, et al. *Ophthalmology*. 2012;119(12):2537–2548. 4. Dugel PU, et al. *Ophthalmology*. 2020;127(1):72–84. 5. Heier JS, et al. *Lancet*. 2022;399(10326):729–740. 6. Lanzetta P, et al. *Lancet*. 2024;403(10432):1141–1152. 7. Holekamp NM, et al. *Ophthalmology*. 2022;129(3):295–307.

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Real-World Anti-VEGF Use Shows As Treatment Intervals Increase, Visual Acuity Decreases



Treatment-Free Interval Increases Over Time in Both Databases

Vestrum Health increases from 6.2 weeks in Year 1 to 8.4 weeks by Year 7
IRIS Registry increases from 8.5 weeks at Year 1 to 12.6 weeks by Year 7

Both Databases Show Early Gains Followed by Long-Term Decline

Vestrum Health: +3.9 letters at Year 1 to -2.1 by Year 7
IRIS Registry: +1.8 letters at Year 1 to -5.0 by Year 7

nAMD Benchmark: Vision and Superiority

NONINFERIORITY TRIALS

VIEW 1 / VIEW 2	Aflibercept 2 mg vs. Ranibizumab ¹
HAWK / HARRIER	Brolucizumab vs. Aflibercept 2 mg ²
CEDAR / SEQUOIA	Abicipar vs. Ranibizumab ³
TENAYA / LUCERNE	Faricimab vs. Aflibercept 2mg ⁴
ARCHWAY	PDS vs. Ranibizumab ⁵
PULSAR	Aflibercept 8mg vs. Aflibercept 2mg ⁶
LUGANO	EYP-1901 vs. Aflibercept 2mg ⁷
DAYBREAK	Tarcocimab & tabirafusp-ted vs. Aflibercept 2mg ⁸

SUPERIORITY TRIALS

VISION	Pegaptanib vs. sham ⁹
MARINA	Ranibizumab vs. sham ¹⁰
ANCHOR	Ranibizumab vs. verteporfin PDT ¹¹
SOL-1	OTX-TKI vs. single Aflibercept 2mg

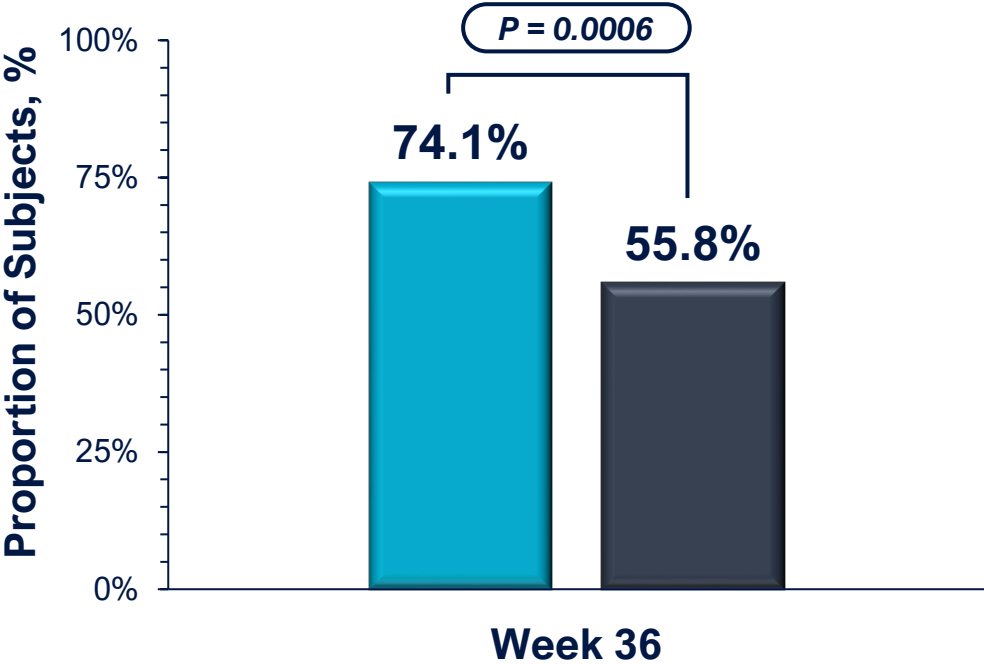
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1. Heier JS, et al. *Ophthalmology*. 2012;119(12):2537–2548. 2. Dugel PU, et al. *Ophthalmology*. 2020;127(1):72–84. 3. Kunimoto D, et al. *Ophthalmology*. 2020;127(10):1331–1344. 4. Heier JS, et al. *Lancet*. 2022;399(10326):729–740. 5. Holekamp NM, et al. *Ophthalmology*. 2022;129(3):295–307. 6. Lanzetta P, et al. *Lancet*. 2024;403(10432):1141–1152. 7. Regillo CD, et al. Presented at: Retina Society Annual Meeting; September 23-26, 2026; Los Angeles, CA. 9. Kodiak Sciences Inc. Zenkuda and Tabirafusp-ted Meet Primary Endpoints in Pivotal DAYBREAK Phase 3 Study. September 28, 2026. 9. Gragoudas ES, et al. *N Engl J Med*. 2004;351(27):2805–2816. 10. Rosenfeld PJ, et al. *N Engl J Med*. 2006;355(14):1419–1431. 11. Brown DM, et al. *N Engl J Med*. 2006;355(14):1432–1444. PDS, port delivery system; PDT, photodynamic therapy

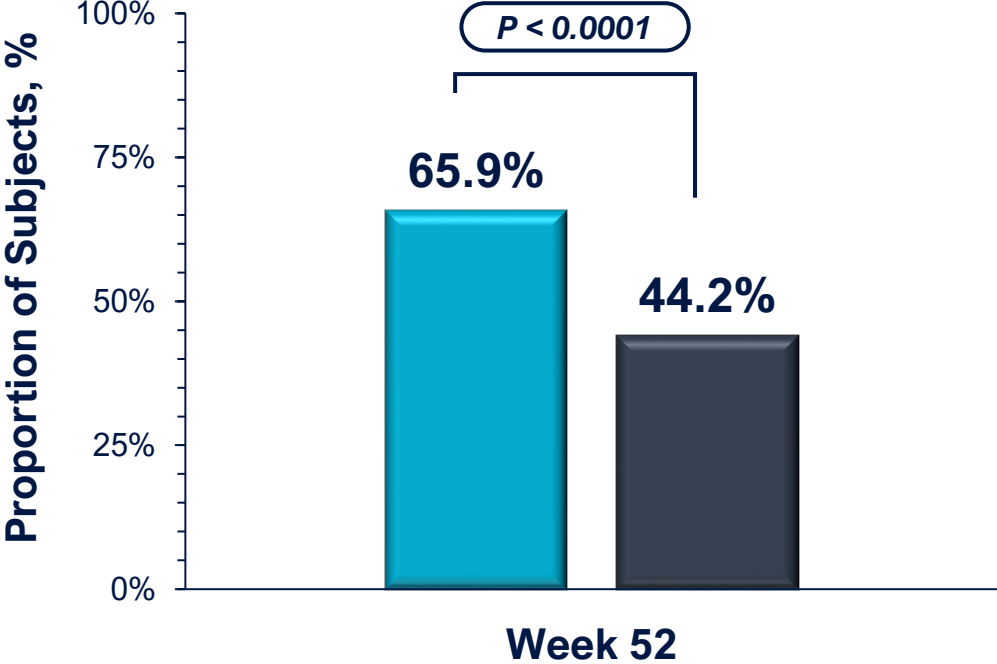
Unmatched Durability: First Trial to Demonstrate Durability ≥ 9 Months

Maintenance of Visual Acuity*

Primary Endpoint



Key Secondary Endpoint



■ OTX-TKI 0.45 mg (n=170) ■ Aflibercept 2 mg (n=172)

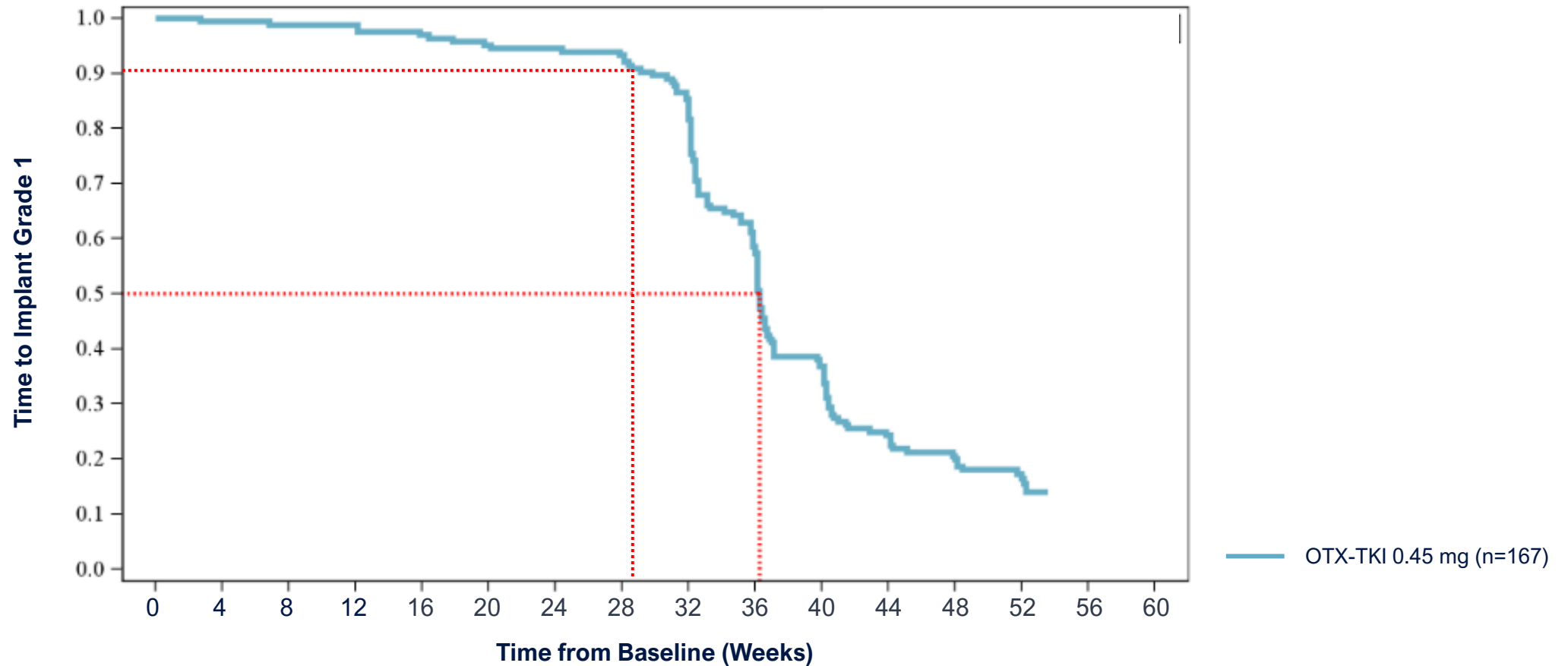
*Maintenance of vision defined as proportion of subjects who maintain visual acuity, a loss of <15 ETDRS letters of BCVA from baseline. Predefined statistical rules were applied to adjust for treatment discontinuation or deviation as per the pre-specified statistical analysis plan. Full analysis set BCVA, best-corrected visual acuity; ETDRS, early treatment diabetic retinopathy study; SD, standard deviation

What is Driving this Sustained Durability?

*How May Early Fluid Control Inform Treatment
Decisions in Clinical Practice?*

OTX-TKI Hydrogel Was Visible in >90% of Patients at Month 6 and ~50% at Month 9

Post Hoc Analysis: Time to Hydrogel Dissipation



**Axitinib release is sustained throughout the period of hydrogel persistence
Residual drug particles continue to provide therapeutic effects for several weeks**

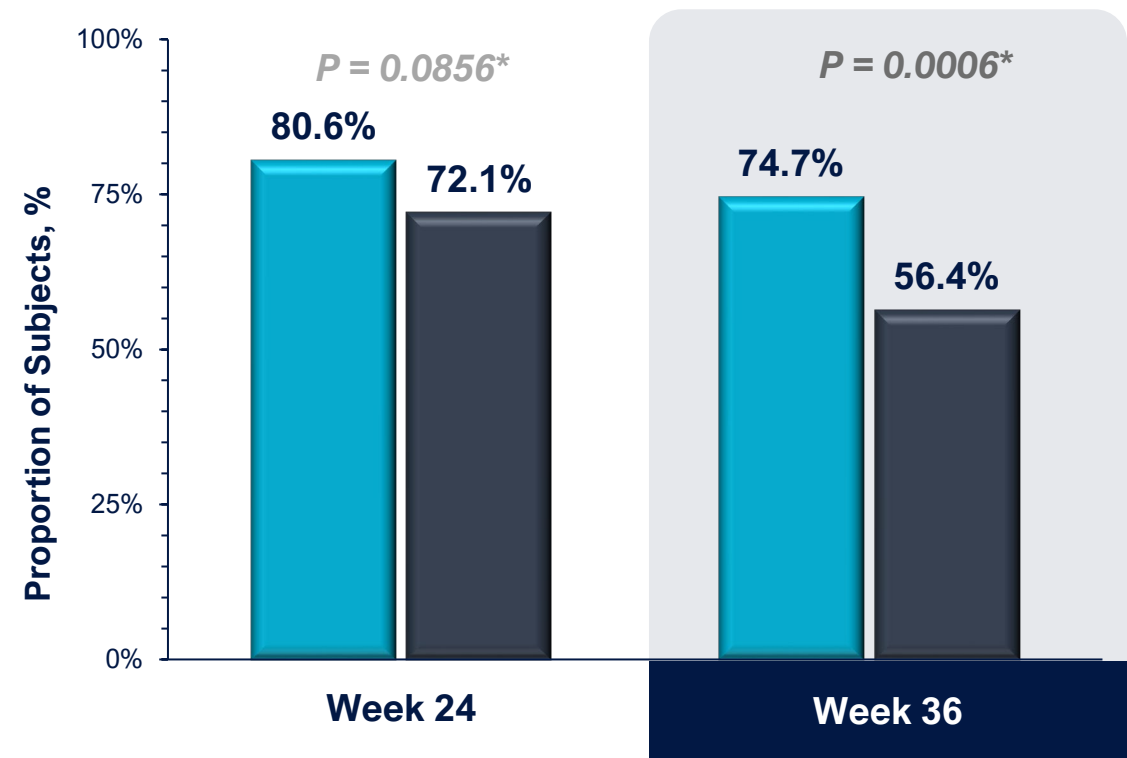
What is Driving this Sustained Durability?

***How May Early Fluid Control Inform Treatment
Decisions in Clinical Practice?***

Most Subjects (~75%) in the OTX-TKI Arm Did Not Receive Supplemental Injections at Week 36

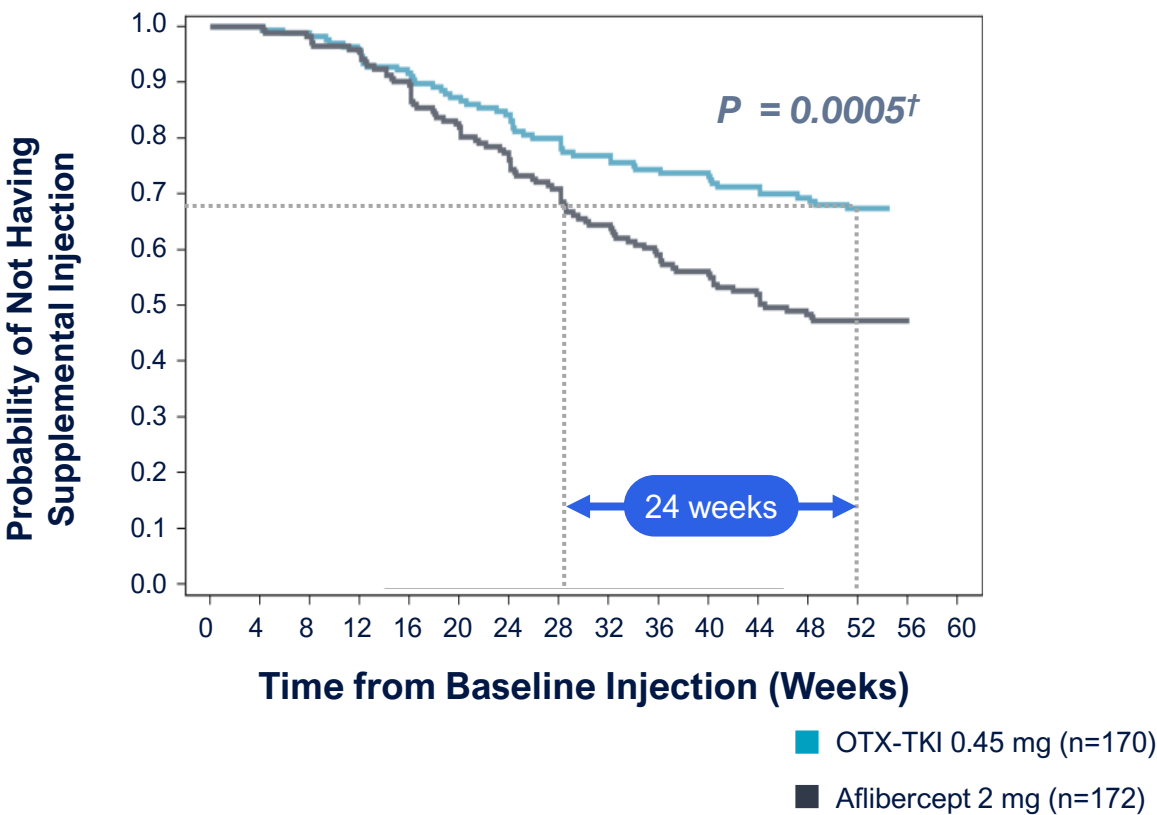
Proportion of Supplemental-free Subjects

Post Hoc Analysis



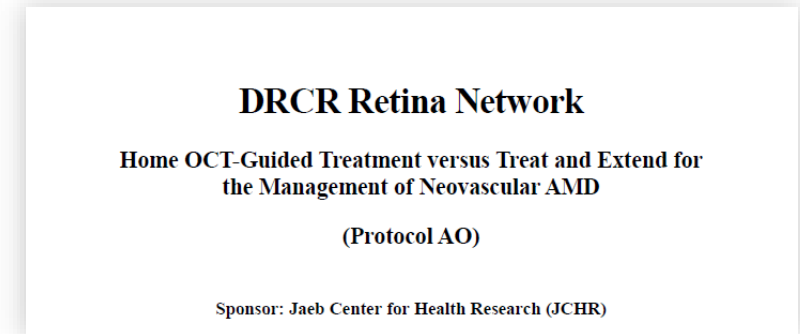
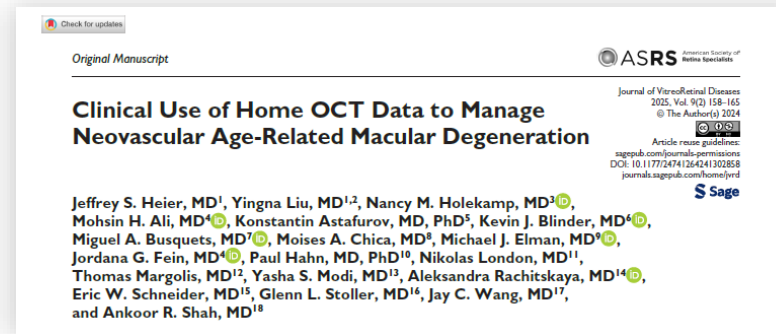
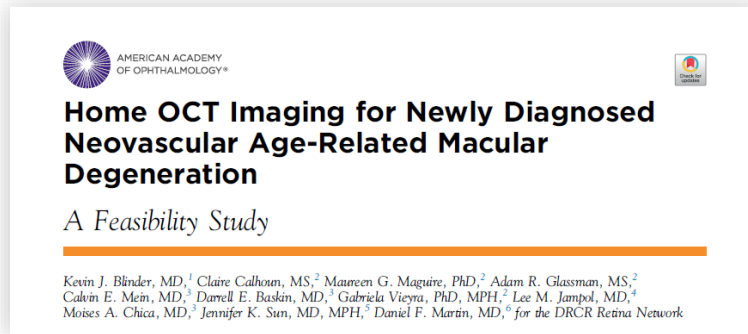
Time to First Supplemental Treatment

Secondary Endpoint



Predefined statistical rules were applied to adjust for treatment discontinuation or deviation as per the pre-specified statistical analysis plan. Full analysis set. Supplemental-free subjects include those who did not require rescue injections as specified by the protocol. At Week 52, the proportion of supplemental-free subjects was 68.8% in the OTX-TKI arm and 47.7% in the aflibercept 2mg arm
*Descriptive p-values; †Nominal P value; Suppl, supplemental

Real-World Retreatment Criteria and Quantitative Dryness (qDry) Using AI-based Retinal Fluid Analysis



Defines Quantitative Dryness

≤10 nL of total retinal fluid was used as the definition of a dry retina¹

Clinically Relevant

10 nL was the median total retinal fluid notification threshold selected by 15 retina specialists²

Implemented Prospectively

DRCR Protocol AO uses 10 nL as the total retinal fluid threshold that triggers an office visit³

Quantitative dryness (qDry) defined as total IRF + SRF ≤10 nL

Most Patients in SOL-1 Demonstrated Retinal Fluid Control with AI-based Retinal Fluid Analysis

Post Hoc Analysis: Patients with *q*Dry Retina at Week 8

Loading Phase		
Change in Fluid Volume from Baseline at Week 8	OTX-TKI 0.45 mg N = 170	Aflibercept 2 mg N = 172
≤10 nL increase (<i>q</i> Dry Retina)	120 (70.6%)	129 (75.0%)
>10 nL increase	44 (25.9%)	36 (20.9%)
Missing data	6 (3.5%)	7 (4.1%)

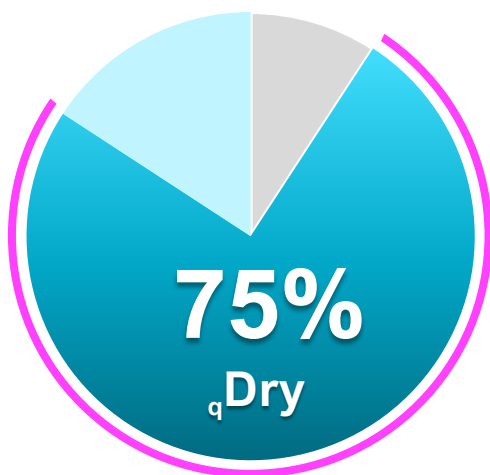
Using Real-world AI-based Retreatment Criteria, 2/3 of OTX-TKI Patients Would Achieve 9-month dosing

SOL-1

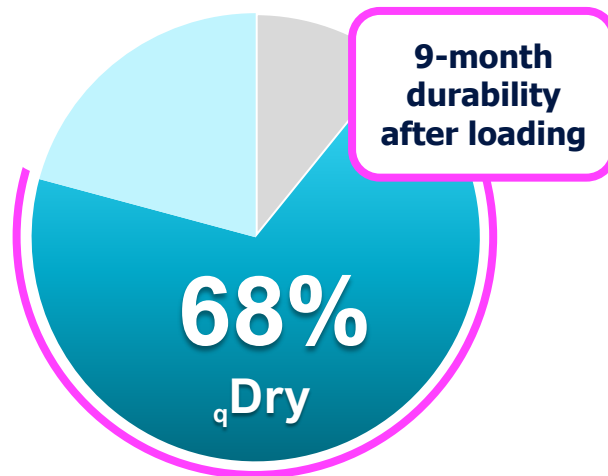
Post Hoc Analysis: Patients with _qDry Retina at Week 8

OTX-TKI 0.45 mg

Week 24



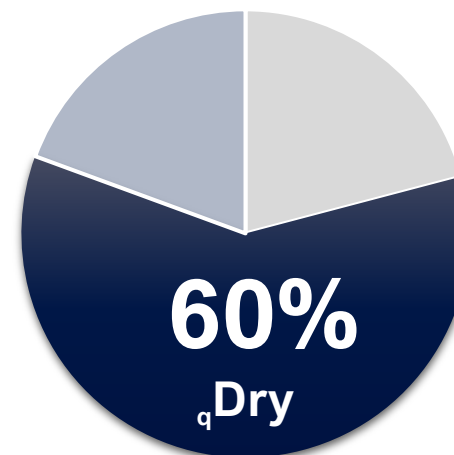
Week 36



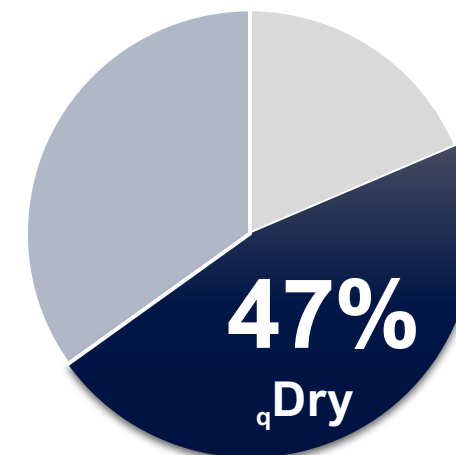
● ≤10nL increase ● >10nL increase ● Missing Data

Aflibercept 2mg

Week 24



Week 36

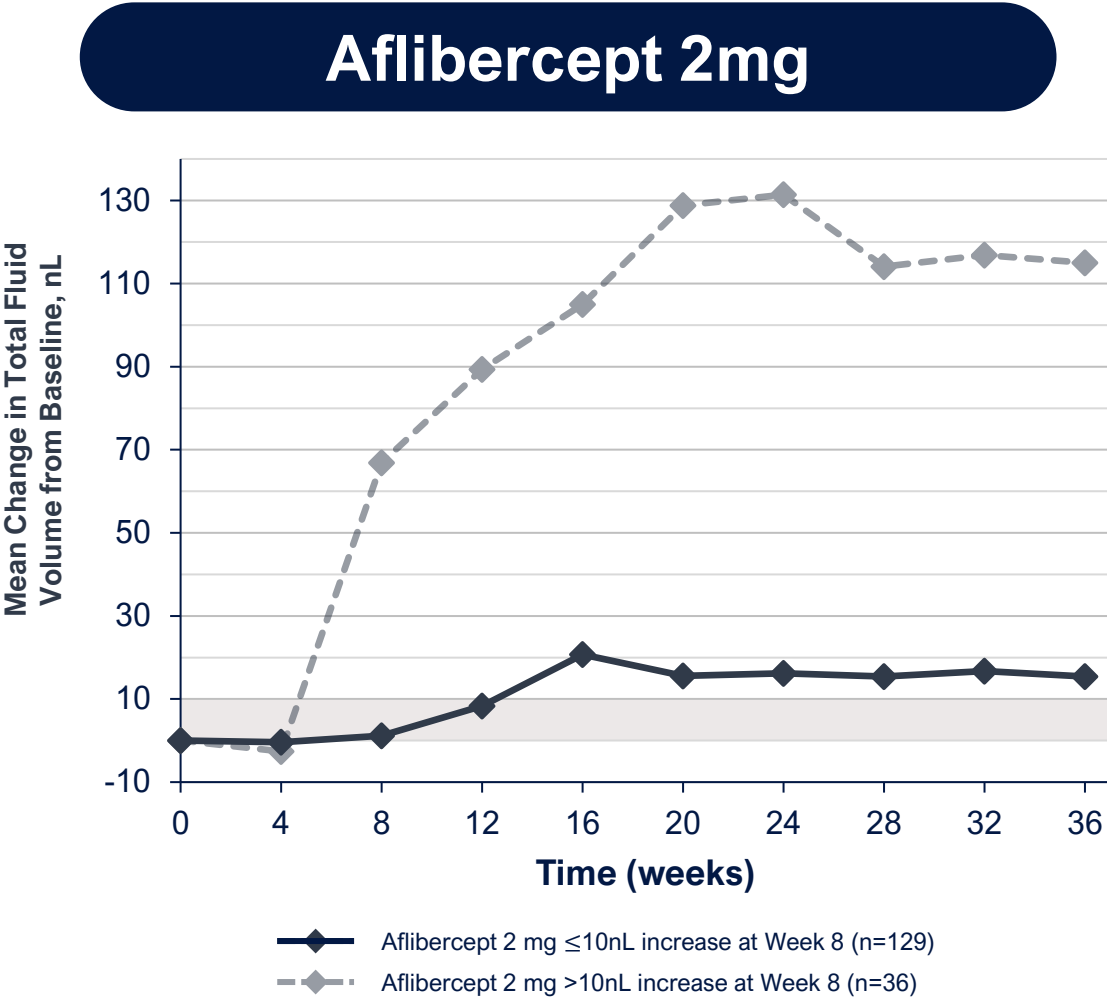
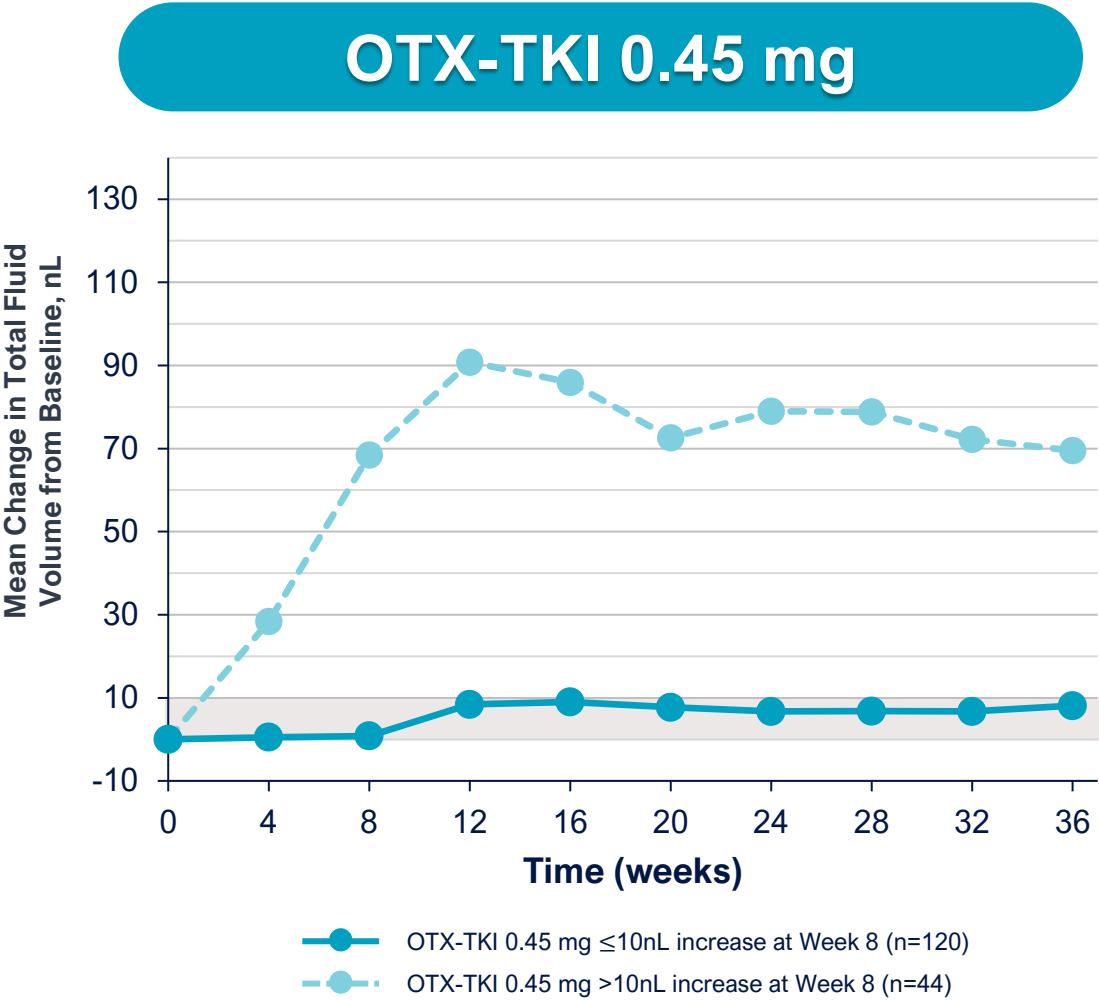


● ≤10nL increase ● >10nL increase ● Missing Data

Patients With Early Fluid Control (~70%) Maintained Their Response through Week 36 with OTX-TKI



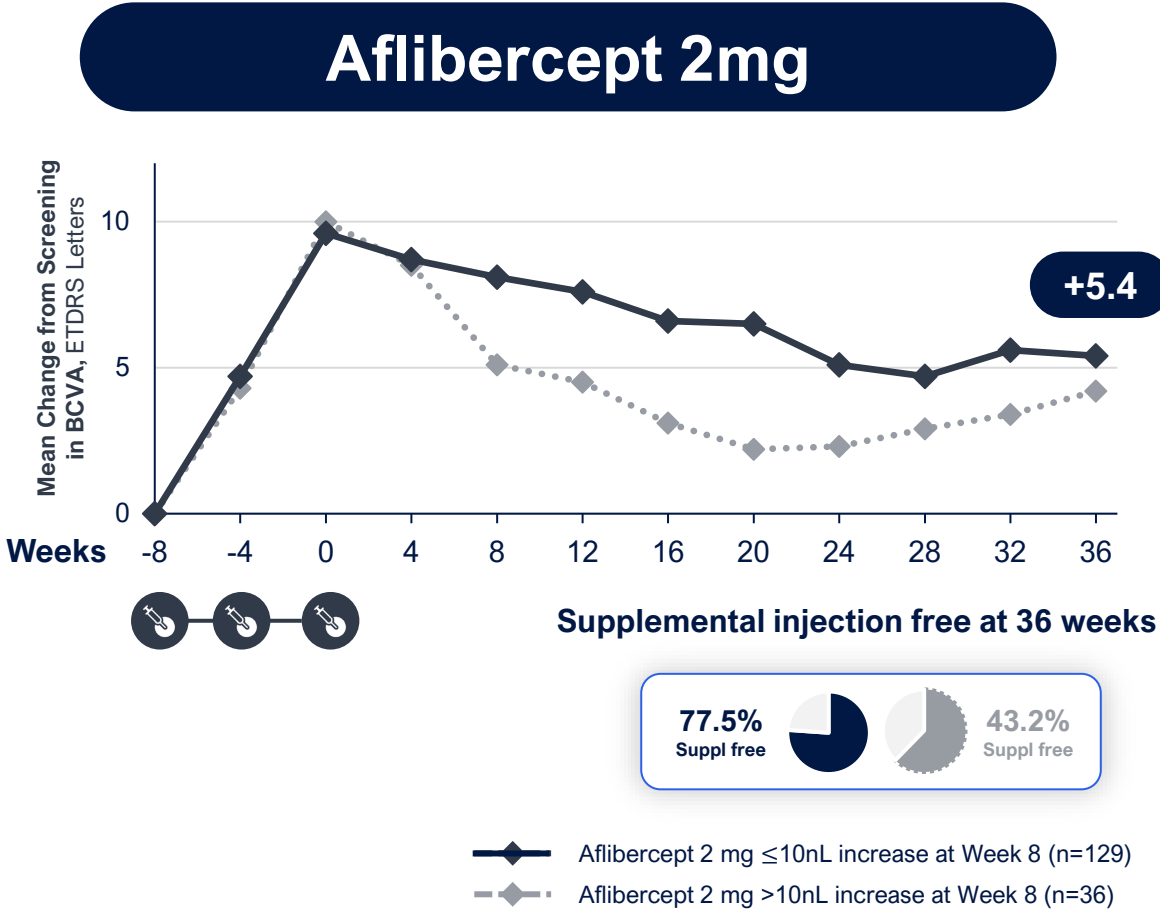
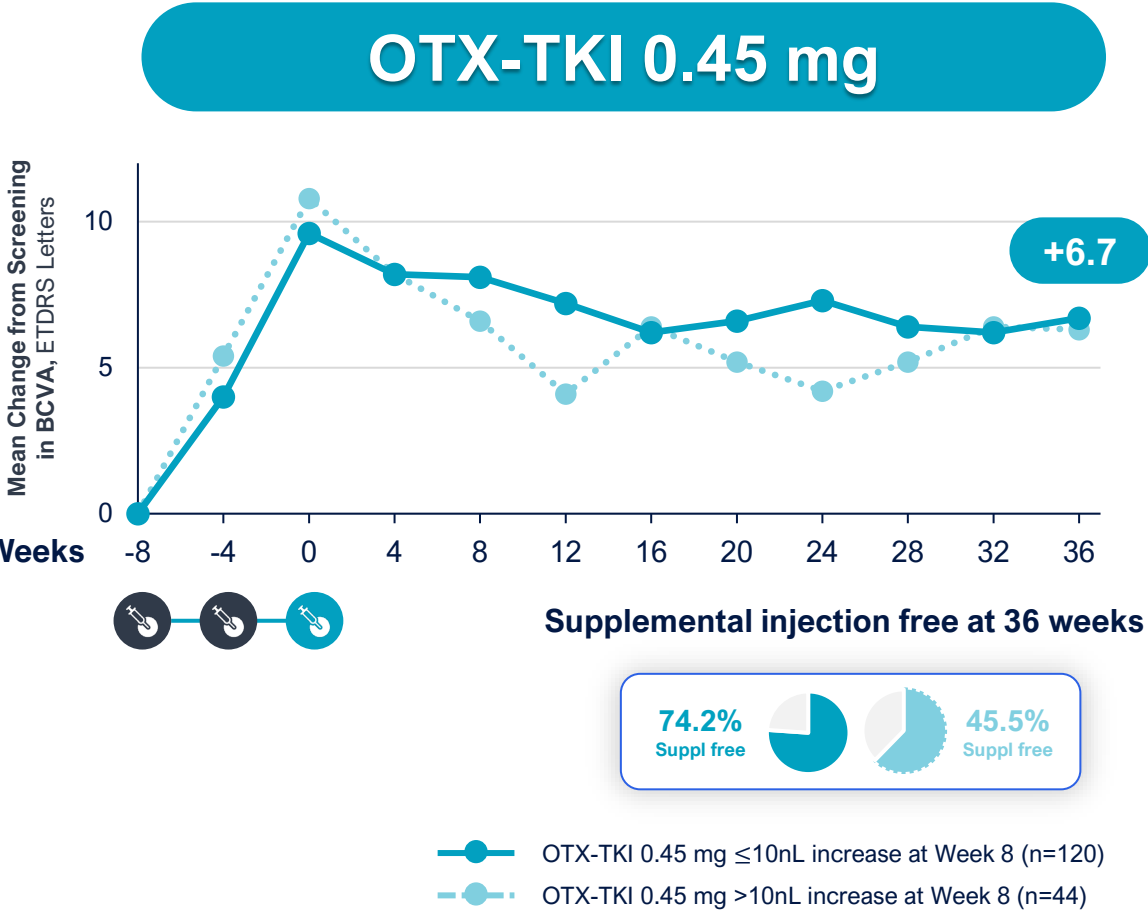
Post Hoc Analysis: Mean Change in Total Retinal Fluid Volume by qDry Status at Week 8



Patients With Early Fluid Control Demonstrated Sustained BCVA Outcomes with OTX-TKI

SOL-1

Post Hoc Analysis: Mean BCVA Change by qDry Status at Week 8



OTX-TKI was Generally Well Tolerated

Subjects with Ocular AEs in the Study Eye (>2%) Through Week 52, n (%)	OTX-TKI 0.45 mg n = 170	Aflibercept 2 mg n = 172
Vitreous floaters	21 (12.4)	2 (1.2)
Cataract	12 (7.1)	5 (2.9)
Conjunctival hemorrhage	11 (6.5)	5 (2.9)
Retinal hemorrhage	10 (5.9)	17 (9.9)
Dry eye	7 (4.1)	2 (1.2)
Vitreous detachment	7 (4.1)	3 (1.7)
Punctate keratitis	6 (3.5)	0
Vitreous opacities	6 (3.5)	0
Eye pain	5 (2.9)	1 (0.6)
Anterior chamber opacity	4 (2.4)	0
Posterior capsule opacification	4 (2.4)	6 (3.5)

Vitreous Floaters

- All cases were mild to moderate in severity
- No evidence of associated IOI
- Onset coincides with drug elution stage of OTX-TKI hydrogel bioresorption process
- For all subjects with vitreous floaters AE reported, drug particles are no longer visible

Intraocular Inflammation

- Nine events observed in study eyes of 7 subjects in the OTX-TKI arm
 - All cases were mild or moderate in severity and resolved
- **There were no cases of endophthalmitis, occlusive or non-occlusive retinal vasculitis**

Key Takeaways

SOL-1 **met its primary endpoint**, demonstrating superiority vs. aflibercept 2 mg in maintenance of visual acuity at Week 36

OTX-TKI hydrogel remained visible in **>90% of patients at Month 6** and ~50% at Month 9

~70% of OTX-TKI treated subjects quantitatively dry at Week 8 continued to be **quantitatively dry through Week 36**



Thank You