

Efficacy and Safety of Intravitreal Axitinib Hydrogel (OTX-TKI) in Neovascular Age-related Macular Degeneration: Results from the Phase 3 SOL-1 Superiority Trial

Dilsher S. Dhoot, MD

Arshad M. Khanani, MD; Patricio G. Schlottmann, MD; Mark R. Barakat, MD; Adnan Tufail, MBBS, MD; Peter K. Kaiser, MD; Jeffrey S. Heier, MD; Nadia K. Waheed, MD on behalf of the SOL-1 study investigators

Retina Society | Los Angeles, CA | September 24, 2026

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

Disclosures and Disclaimer

Financial Disclosures (Dilsher S. Dhoot):

- Consultant: 4DMT, Abbvie, Adverum, Alcon Pharmaceuticals, Alimera Sciences, Inc., Alkeus, Allergan, ANI Pharmaceuticals, Amgen, Annexon, Apellis Pharmaceuticals, Inc., Astellas; Bausch and Lomb, Bayer Healthcare Pharmaceuticals, Inc., Biocryst, Coherus, EyePoint Pharmaceuticals, Genentech, Harrow, IvericBio, Novartis, Ocular Therapeutix, Oculis, Optos, Inc., Opthea, Outlook Therapeutics, Oxular, Regeneron, REGENXBIO, RetinaAI, Roche, Sanofi, Santen, Inc.
- Research Support: 4DMT, Adverum, Annexon Biosciences, Eyebio, Eyepoint Pharma, Genentech, Kodiak Sciences, Ocular Therapeutix, Inc, Oculis, Ophthea, Regeneron, RegenxBio, Sanofi.
- Speaker: Amgen, ANI Pharmaceuticals, Apellis, Genetech, Regeneron

Investigational Product Disclosure

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.

Study Design: OTX-TKI and Aflibercept Direct Comparison

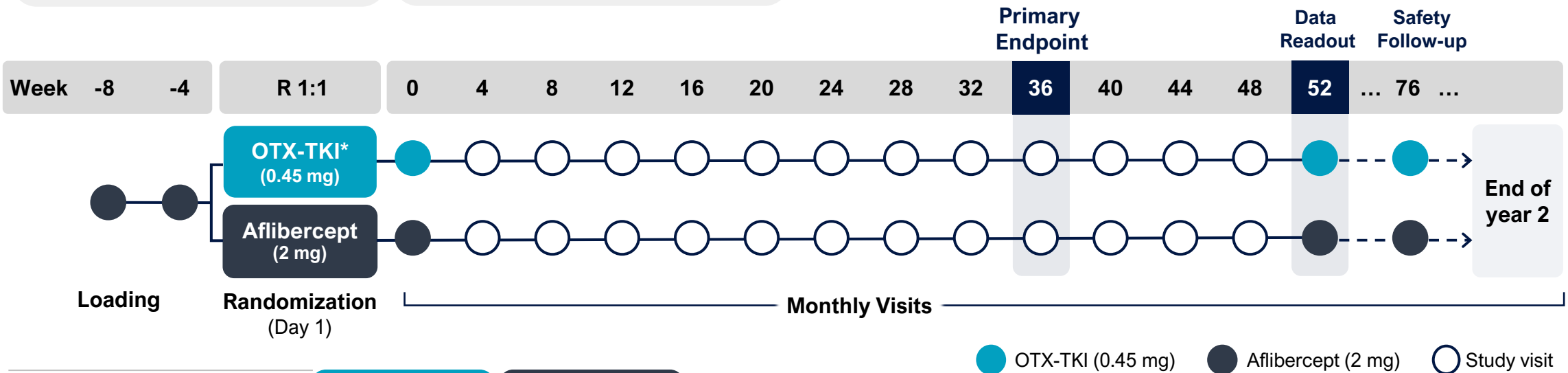
Key Enrollment Criteria (Screening)

- Treatment naïve for nAMD
- **BCVA ≥ 54 ETDRS letters** (~20/80)
- **CSFT of ≤ 500 μm**

Key Randomization Criteria (Day 1)

- **BCVA gain ≥ 10 ETDRS letters**
OR
BCVA ≥ 84 ETDRS letters (~20/20)
- **CSFT of ≤ 350 μm**

Proportion of subjects who maintained visual acuity, defined as <15 ETDRS letters of BCVA loss from baseline at Week 36



Baseline (Randomization) Study Eye Characteristics	OTX-TKI 0.45 mg N = 172 [†]	Aflibercept 2 mg N = 172
Mean (SD) BCVA, ETDRS letter score, Snellen Equivalent	80.8 (7.6) ~20/25	79.2 (7.9) ~20/25
Mean (SD) CSFT, μm ,	219.3 (37.1)	226.8 (42.1)

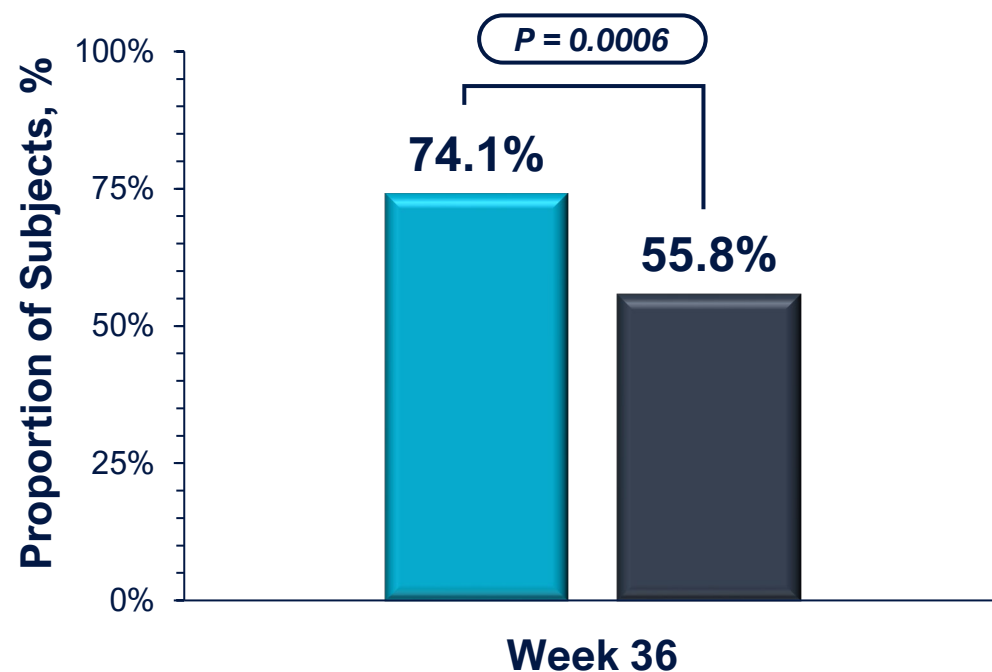
*No aflibercept injection is given at baseline;
[†]Two OTX-TKI subjects were misrandomized, did not receive study treatment and were not included in the full analysis set
ClinicalTrials.gov. identifier: NCT06223958

Rescue Criteria: BCVA loss ≥ 15 ETDRS letters from baseline due to nAMD; or New macular hemorrhage that would likely lead to irreversible vision loss if left untreated in the opinion of the investigator after discussion with Medical Monitor
BCVA, best-corrected visual acuity; CSFT, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; SD, standard deviation

Unmatched Durability: First Trial to Demonstrate Durability >9 Months SOL-1

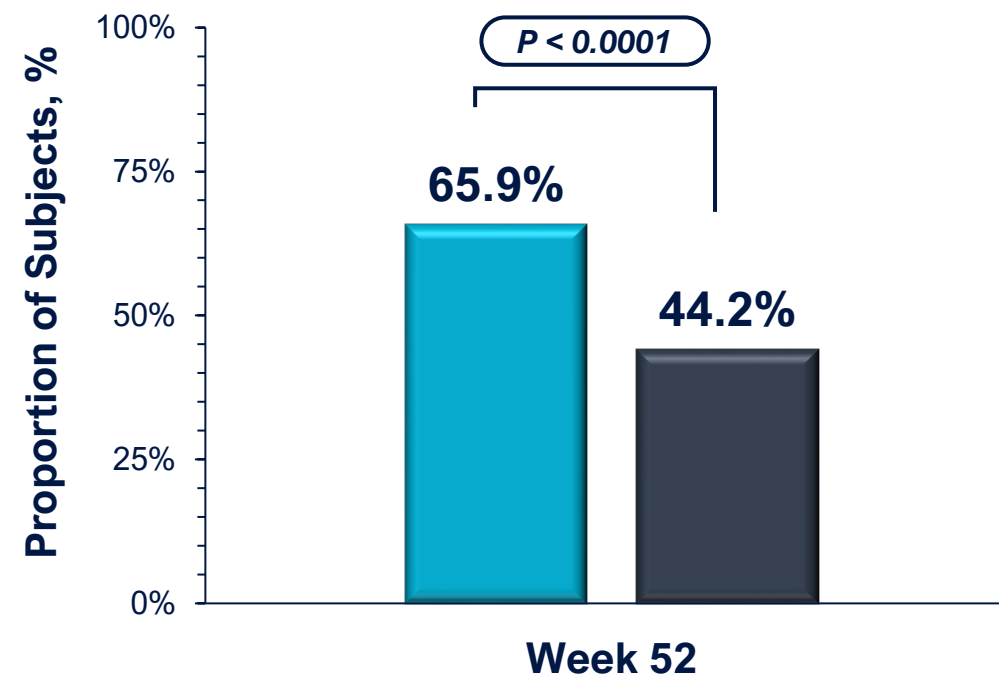
Maintenance of Visual Acuity* at Week 36

Primary Endpoint



Maintenance of Visual Acuity* at Week 52

Key Secondary Endpoint

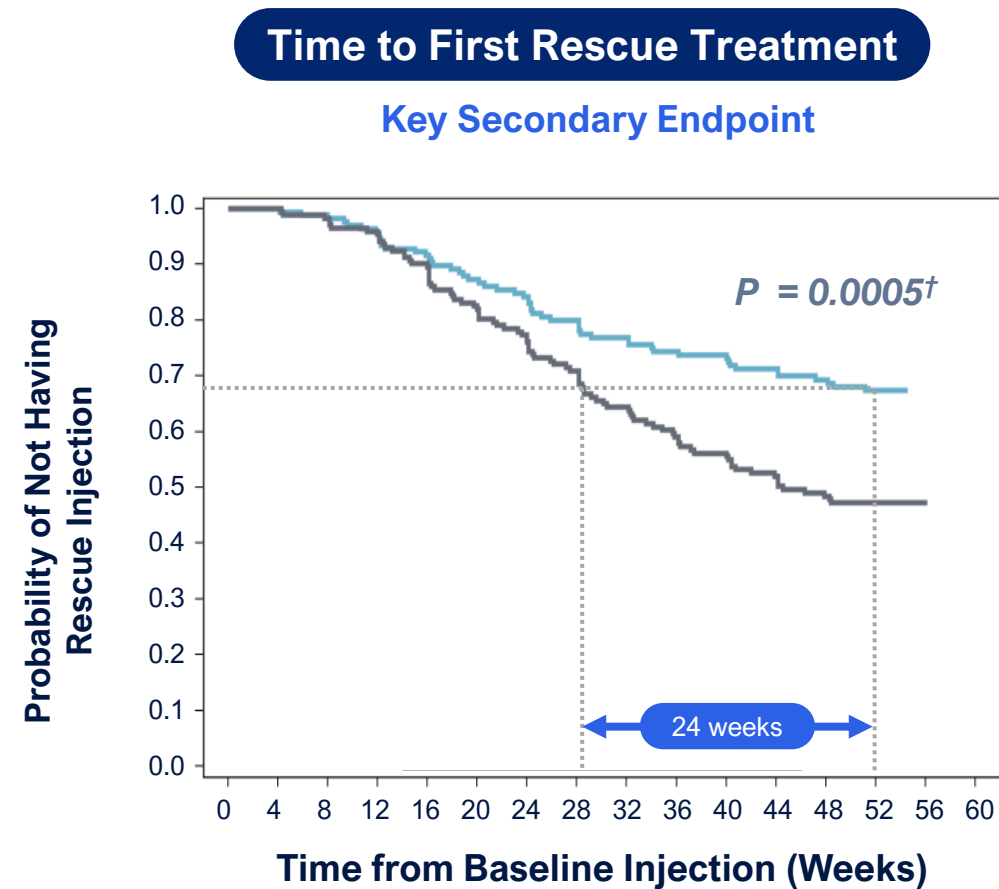
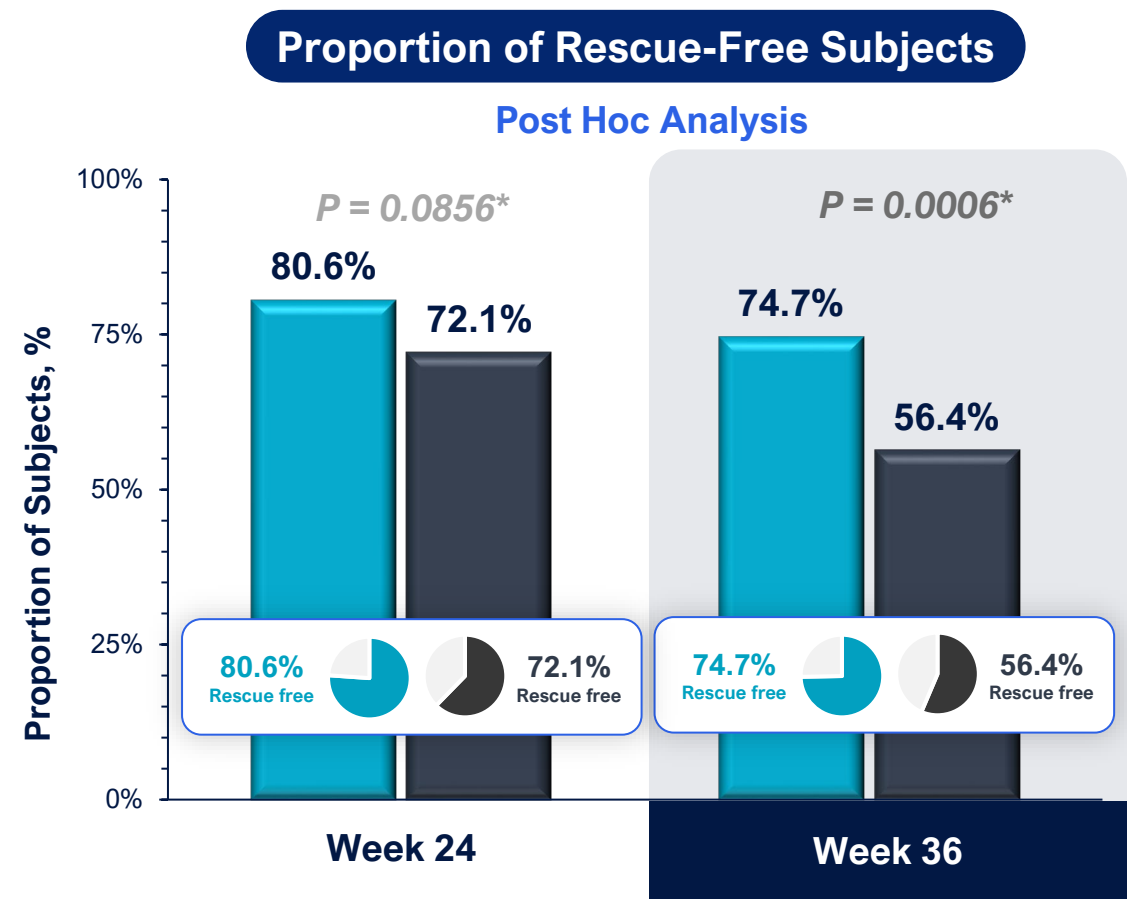


■ OTX-TKI 0.45 mg (n=170) ■ Aflibercept 2 mg (n=172)

*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

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

SOL-1



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

OTX-TKI 0.45 mg (n=170)

Aflibercept 2 mg (n=172)

Treatment Burden Reduction vs 2 mg Aflibercept Q8W at ~1 Year

	LOADING DOSES INCLUDED	LOADING DOSES <u>NOT</u> INCLUDED
Faricimab TENAYA/LUCERNE ^{1,2} Phase 3 - to Week 48	14% (6.4 vs 7.4)	45% (2.4 vs 4.4)
Aflibercept 8mg PULSAR ^{3,4} Phase 3 – up to Week 48	29% (5.49 vs 7.7) (weighted mean Q12 and Q16 arms)	47% (2.49 vs 4.7) (weighted mean Q12 and Q16 arms)
4D-150 PRISM ⁵ Phase 2b (3E10 dose)* - through Week 52	50% (3.97 vs 8) vs projected on-label aflibercept 2 mg control	51% (2.97 vs 6) vs projected on-label aflibercept 2 mg control
ADVM-022 LUNA ⁶ Phase 2 (2E11 dose)*	65% (2.8 vs 8) vs projected on-label aflibercept 2 mg control	70% (1.8 vs 6) vs projected on-label aflibercept 2 mg control
RGX-314 Subretinal Phase 2 Study ^{7,8} (Low dose/High dose annualized)†	58 - 60% (3.2/3.4 vs 8) vs projected on-label aflibercept 2 mg control	60 - 63% (2.2/2.4 vs 6) vs projected on-label aflibercept 2 mg control
EYP-1901 2.7mg LUGANO ⁹ Phase 3 – up to Week 56	27% (6.1 vs 8.3)	42% (3.1 vs 5.3)
OTX-TKI Post hoc analysis of estimated treatment burden reduction in SOL-1 Phase 3 (using SOL-R supplemental injection criteria)	56% (3.95 vs 9)‡ vs projected on-label aflibercept 2 mg control	72% (1.95 vs 7) vs projected on-label aflibercept 2 mg control

*Previously treated wet age-related macular degeneration population; † Does not include the subretinal surgery as a treatment; ‡ OTX-TKI durability measured over 60 weeks to include loading doses at Week-8 and Week-4.

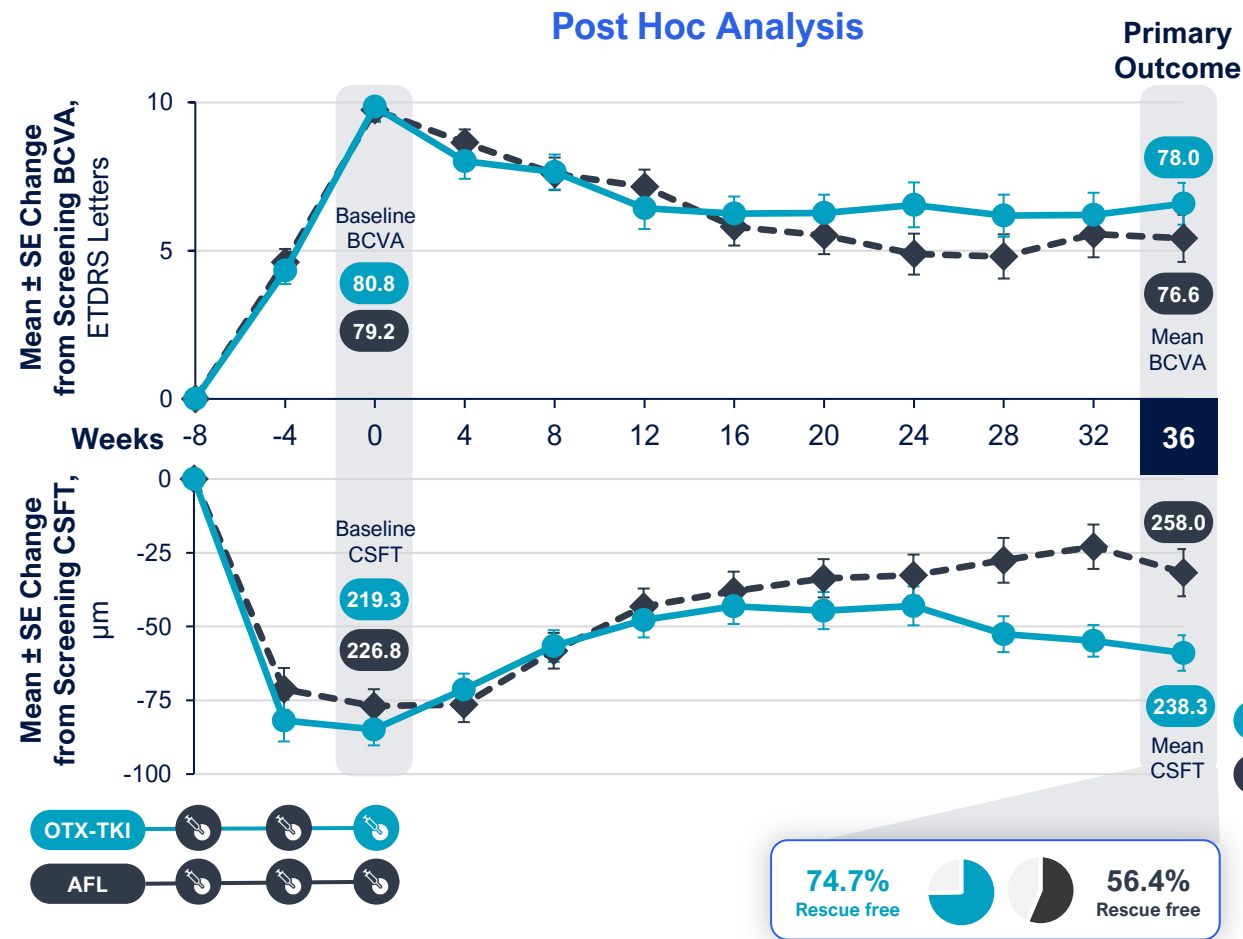
The data presented here include a comparison of results from distinct clinical trials. These studies featured varying inclusion and exclusion criteria, baseline characteristics, and patient demographics which may significantly impact clinical outcomes. Because comparisons between these trials may not 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.

Treatment burden calculations use reported treatment counts in the investigational arms relative to a projected on-label aflibercept (2 mg) dosing schedule. Actual on-label aflibercept (2 mg) dosing schedules were used where available. For aflibercept 8mg, results from the Q12 and Q16 arms were combined using a sample-size-weighted mean. Loading doses were defined as regimen-specific administrations occurring before the maintenance or durability phase and were included or excluded as indicated.

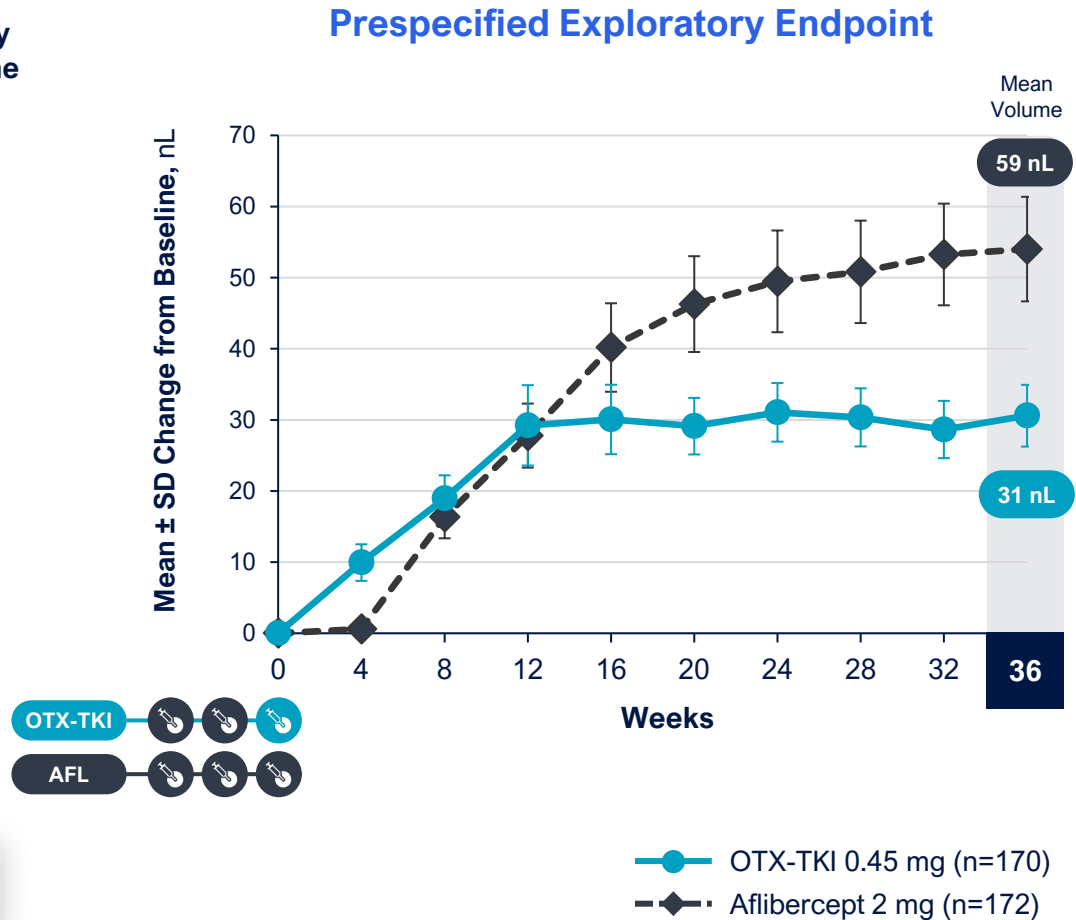
1. Heier JS, et al. *Lancet*. 2022;399(10326):729-740. 2. FDA. Vabysmo clinical review. BLA 761235. 2021. 3. Lanzetta P, et al. *Lancet*. 2024;403(10432):1141-1152. 4. FDA. Eylea HD (aflibercept): BLA 761355 Summary Review. 2023. Table 31. 2024. 5. Pieramici D. Presented at: Angiogenesis, Exudation, and Degeneration 2025; February 8, 2025. https://4dmoleculartherapeutics.com/wp-content/uploads/Angiogenesis-2025-PRISM-Ph2b-Dante_vF_08-Feb-2025.pdf 6. Wykoff CC. Presented at: FLORetina 2025; December 4-7, 2025; Florence, Italy. https://adverum.com/wp-content/uploads/FLORETINA-2025_LUNA-2-year-Results.pdf 7. Tuli R. Subretinal delivery of investigational ABBV-RGX-314 for nAMD. Canadian Retina Society; 2025. 8. Data on File. Ocular Therapeutix. 9. EyePoint Inc. LUGANO phase 3 clinical trial: DURAVYU in wet AMD—expanded results and analyses. Investor presentation. Published September 2026. Accessed September 16, 2026. <https://investors.eyepoint.bio/static-files/7e8b3b5e-2f94-4f34-8d97-586752ec3cb2>

Sustained Disease Control: Visual and Anatomic Stability with OTX-TKI SOL-1

Mean Change in BCVA and CSFT from Screening



Mean Change in Retinal Fluid Volume



Full analysis set. For subjects who received any rescue injections, their observed BCVA and CSFT values after the 1st rescue injection are set to missing. Baseline measurements are the last non-missing measurement prior to the study drug injection on Day 1. AFL, aflibercept; BCVA, best-corrected visual acuity; CSFT, central subfield thickness, measured from the internal limiting membrane to the retinal pigment epithelium; ETDRS, Early Treatment Diabetic Retinopathy Study; IRF, intraretinal fluid; SRF, subretinal fluid; SE, standard error; SD, standard deviation

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

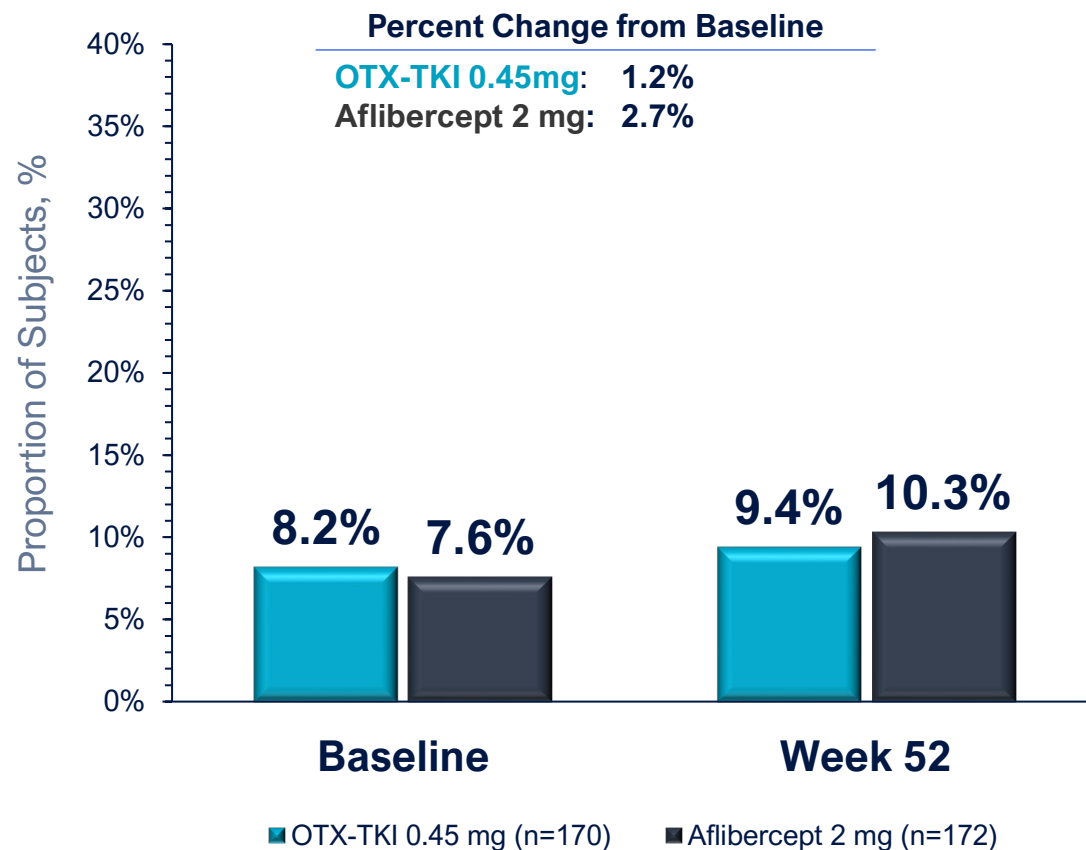
Intraocular Inflammation

- 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**

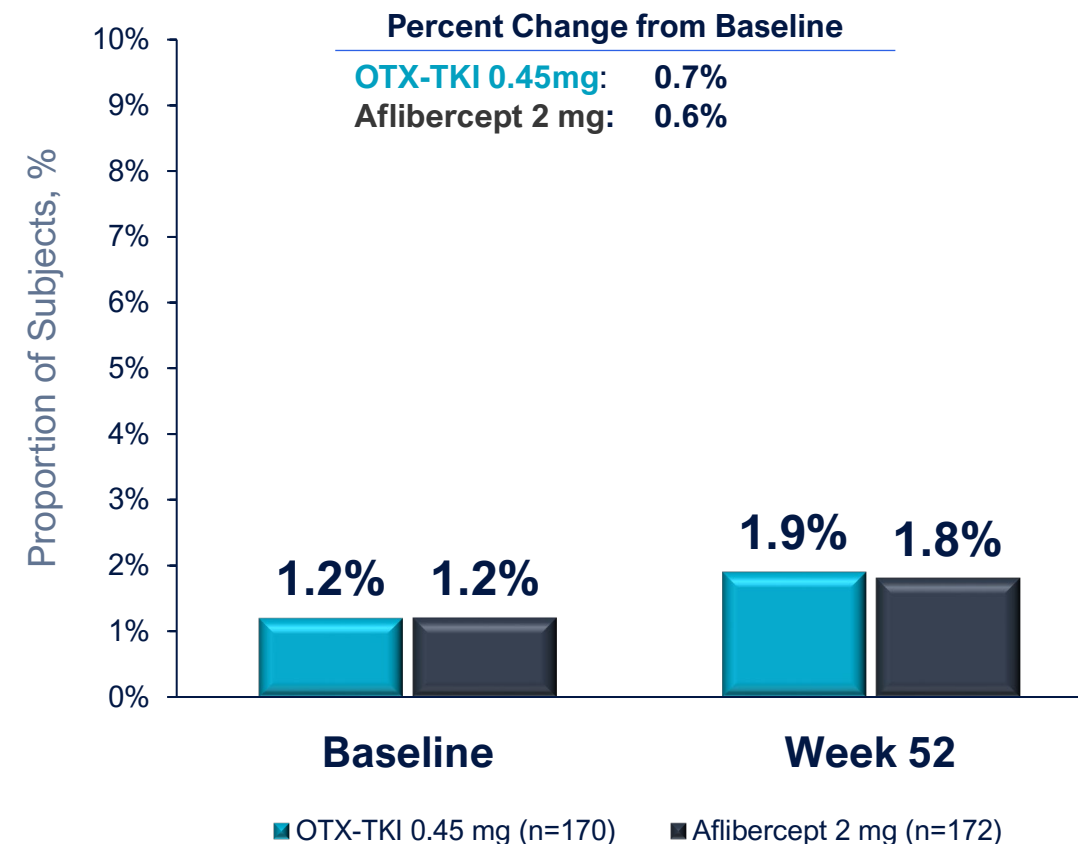
Incidence of Macular Atrophy in SOL-1

Safety Analysis

Any Macular Atrophy¹



Macular Atrophy in the Central 1mm¹



¹cRORA measured by the reading center

cRORA, complete retinal pigment epithelium and outer retinal atrophy

Superiority Primary Endpoint Successfully Met

OTX-TKI Demonstrated Superior Maintenance of Vision Compared to Aflibercept 2mg at Week 36*

First trial to demonstrate durability ≥ 9 months

In a post hoc analysis, 74.7% of subjects treated with OTX-TKI did not receive rescue treatments by Week 36

Unmatched Durability

Visual and anatomic stability with OTX-TKI

In a post hoc analysis, OTX-TKI subjects maintained visual and anatomical outcomes, with most remaining rescue-free through Week 36

Sustained Disease Control

OTX-TKI demonstrated a well-tolerated safety profile through Week 52

There were no cases of endophthalmitis, occlusive or non-occlusive retinal vasculitis

Well-Tolerated

OTX-TKI is an investigational product candidate which has not been approved by the FDA or any regulatory authority.

*Maintenance of vision defined as proportion of subjects who maintain visual acuity, a loss of <15 ETDRS letters of BCVA from baseline
Rescue-free subjects include those who did not require rescue injections as specified by the protocol