Efficacy and Safety of Intravitreal Axitinib Hydrogel (OTX-TKI) in Neovascular Age-related Macular Degeneration: Week 52 Results from the Phase 3 SOL-1 Superiority Trial

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Disclosures and Disclaimers

Adnan Tufail

- Consultant: 4DMT, Adverum, Annexon, Apellis, Aviceda, Boehringer Ingleheim, Eyebio, Astellas, Janssen, Kanghong, Nanoscope, Novartis, OcuTerra, Ocular Therapeutix, Regenxbio, Roche/Genentech
- Stockholder: Oculogics, Cellio
- Research support: Novartis, Bayer

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

Study Design: OTX-TKI and Aflibercept Direct Comparison

SOL-1

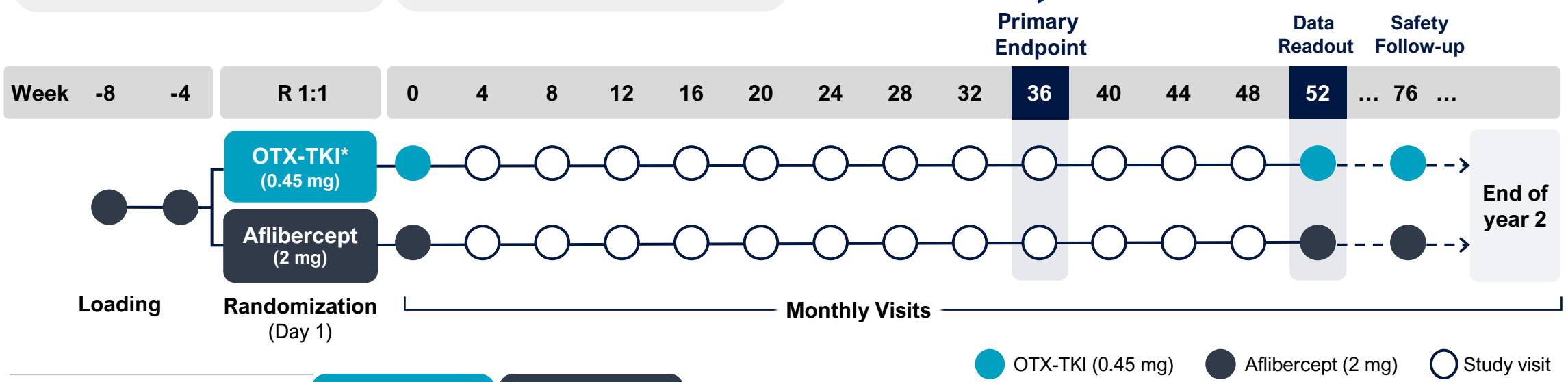
Key Enrollment Criteria (Screening)

- 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)

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*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

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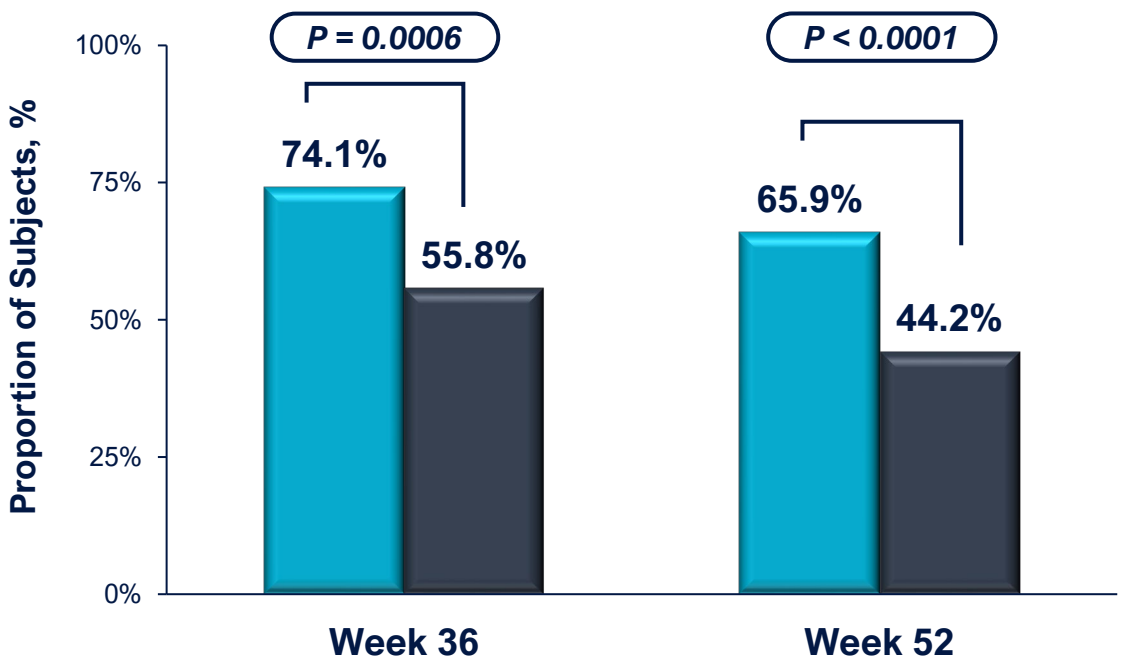
Maintenance of Visual Acuity*

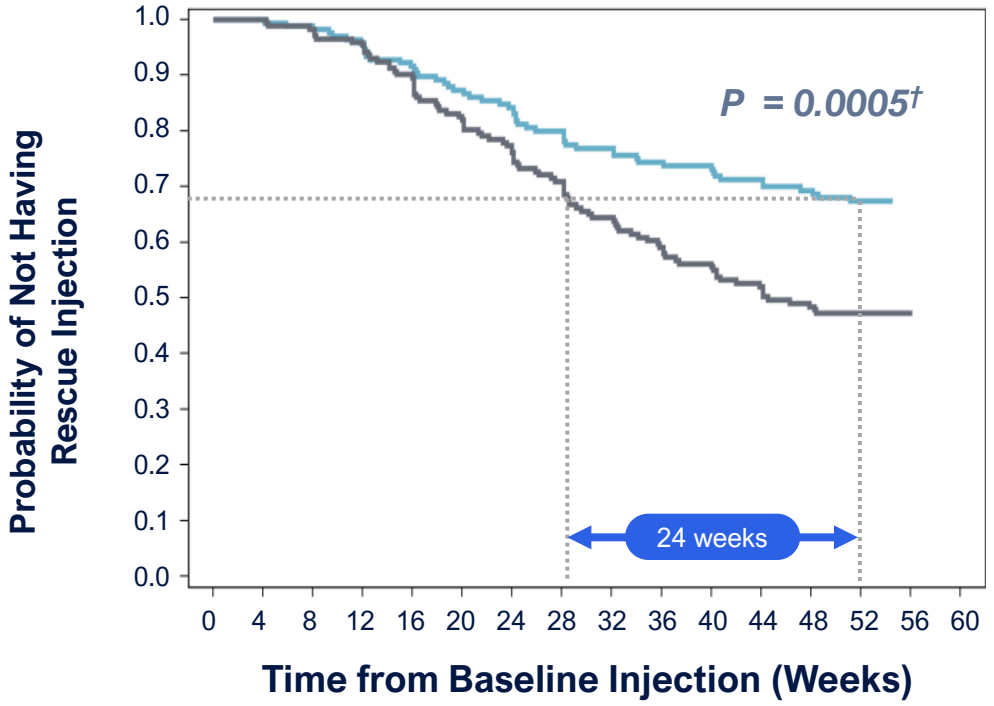
Primary Endpoint

Key Secondary Endpoint



Time to First Rescue Treatment

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

†Nominal P value

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.

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study

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

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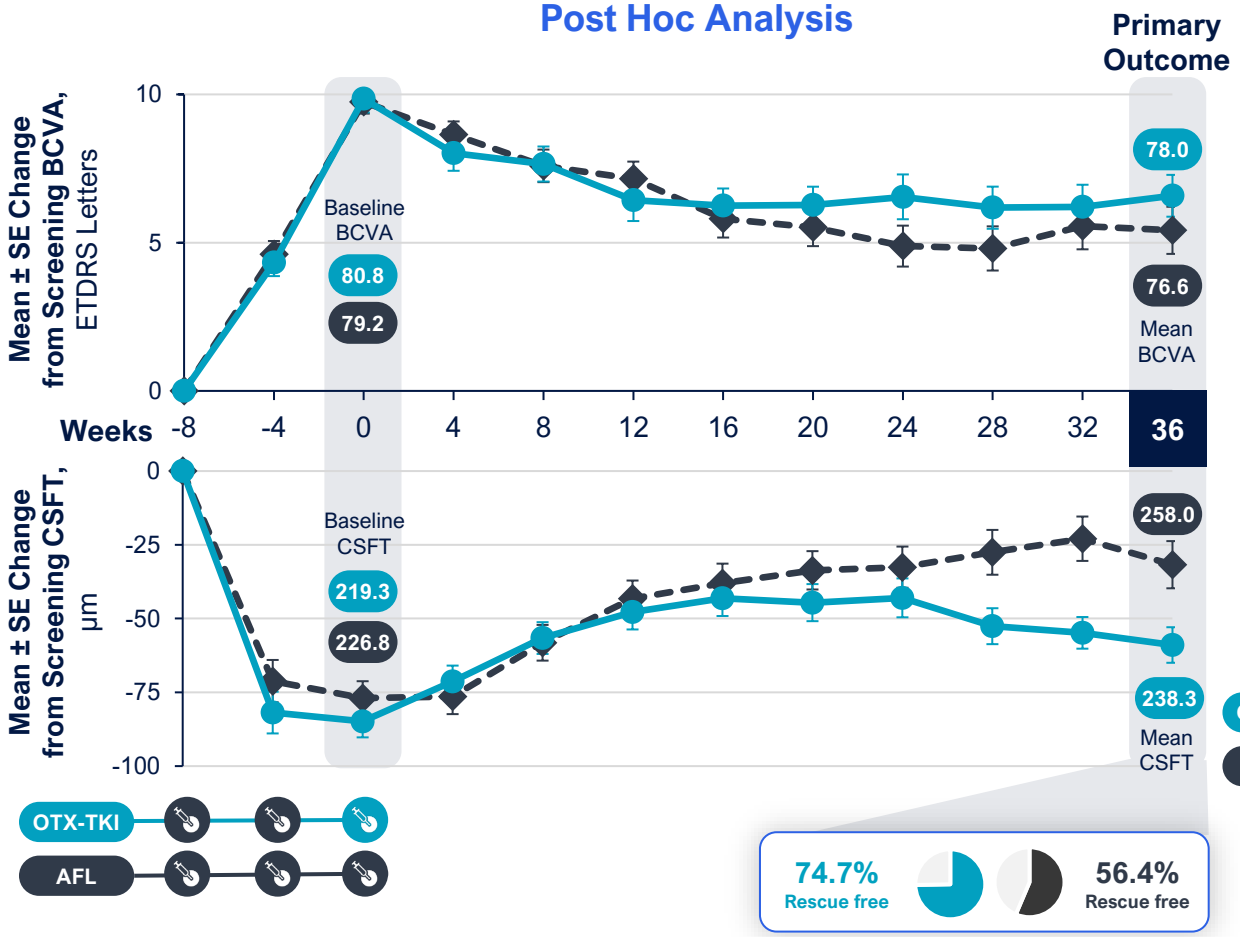
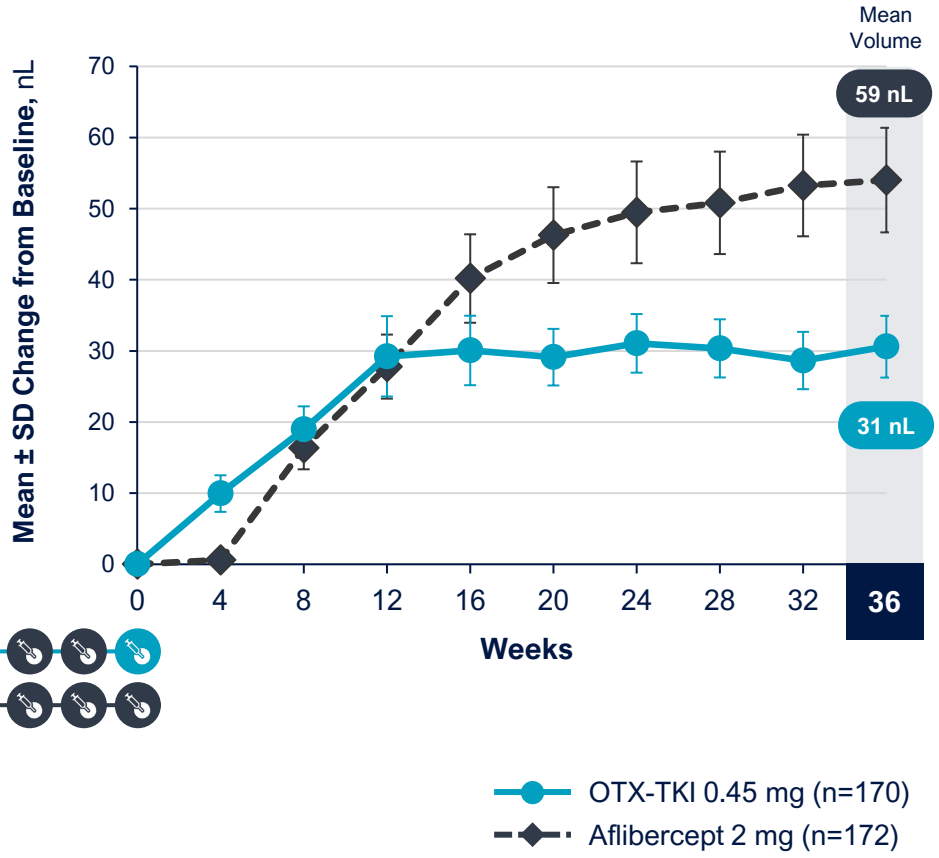
Mean Change in BCVA and CSFT from Screening

Post Hoc Analysis



Mean Change in Retinal Fluid Volume

Prespecified Exploratory Endpoint



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

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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**

AE, adverse event; IOI, intraocular inflammation

SOL-1 Results Demonstrate Potential Treatment Benefit of OTX-TKI

SOL-1

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.

OCULAR THERAPEUTIX Retina experience redefined

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