

Redefining the Management of nAMD

The Impact of Durability and Sustained Disease Control

October 2, 2026

Euretina | Vienna, Austria



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Any statements in this presentation about future expectations, plans, and prospects for the Company, including statements regarding the development and regulatory status of the Company's or its competitors' product candidates, including statements regarding the SOL-1 Phase 3 superiority trial being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. FDA and aligned with FDA draft guidance for neovascular AMD drug development; the timing, design, enrollment, randomization, conduct and retention of subjects in the Company's clinical trials, including the Company's SOL-1 trial and its SOL-R Phase 3 non-inferiority trial and SOL-X open-label extension trial of OTX-TKI for the treatment of wet age-related macular degeneration (wet AMD), also known as neovascular age-related macular degeneration (nAMD); statements regarding the potential utility or adoption of OTX-TKI or its competitors, if approved; statements regarding the Company's intention to submit a new drug application for OTX-TKI, based on data from the Company's SOL-1 trial in wet AMD, subject to planned formal discussions with the FDA; and other statements containing the words "anticipate", "become", "believe", "estimate", "expect", "intend", "designed", "goal", "may", "might", "plan", "position", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue", and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. 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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

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Consultant Ophthalmic Surgeon at Moorfields Eye Hospital NHS Foundation, London, UK



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Director of Research, Charles Ophthalmic Center and Ophthalmology Department Director at Organización Médica de Investigación, Buenos Aires, Argentina

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, 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, Ceryvyn Therapeutics, Regeneron, RegenxBio, Sanofi.
- **Speaker:** Amgen, ANI Pharmaceuticals, Apellis, Genetech, Regeneron

Arshad M. Khanani

- **Consultant:** Abbvie, ADARx Pharmaceuticals, Adverum, Alcon, Alkeus, Allgenesis, Amgen, Annexin, Annexon, Apellis Pharmaceuticals, Ashvattha, Therapeutics, Astellas, Aviceda Therapeutics, Beacon Therapeutics, Boehringer Ingelheim, Clearside Biomedical, Complement Therapeutics, Ceryvyn Therapeutics, 4DMT, Entarada, Exegenesis, EyePoint Pharmaceuticals, Fronterra Therapeutics, Genentech, Harrow, i-Lumen Scientific, InFocus, Janssen Pharmaceuticals, Kriya Therapeutics, Kyowa Kirin, Lexitas, Merit, Neurotech, Nanoscope, Novartis, Ocugen, Ocular Therapeutix, Oculis, Ollin, Opus Genetics, Perfuse, Recens Medical, Regeneron Pharmaceuticals, Regenxbio, Revive, RevOpsis, Roche, Samsung, Sanofi, Stealth BioTherapeutics, Sun Pharma, Surrozen, Thea Pharma, Therini, Unity Biotechnology, Vanotech, Vial, ZipBio
- **Research support:** Aviceda, Adverum, Alexion, Annexon, Astellas, Aviceda Therapeutics, Biojiva Complement Therapeutics, Ceryvyn Therapeutics, 4DMT, Eyepoint Pharmaceuticals, Exegenesis, Genentech, Gyroscope Therapeutics, Janssen, Kyowa Kirin, Ocular, Ollin, Therapeutix, Regenxbio, Roche, Sanofi, Vanotech
- **Stock/Stock options:** Ashvattha, Aviceda Therapeutics, Ocular Therapeutix, Oculis, Ollin, PolyPhotonix, Recens Medical, Perfuse, RevOpsis, Vial, ZipBio
- **Board of Directors:** Oculis

Patricio G. Schlottmann

- **Consultant:** Ocular Therapeutix, Novartis, Roche/Genentech, Janssen, Ora, Nanoscope, EyeBio/Merck, 4DMT, Kodiak, Oculis, Abbvie, Horizon Surgical, Adverum, Revopsis, Merit, Amgen, Kodiak
- **Research support:** Ocular Therapeutix, 4DMT, EyeBio/Merck, Roche/Genentech, Priovant, Kodiak

Adnan Tufail

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

Agenda

Opening Remarks

Arshad M. Khanani, MD, MA, FASRS

The Unmet Need

Adnan Tufail, MBBS, MD, FRCOphth

Science Behind the Therapy

Dilsher S. Dhoot, MD, FASRS

SOL-1 Trial Design & Baseline Characteristics

Arshad M. Khanani, MD, MA, FASRS

SOL-1 Results

Patricio G. Schlottmann, MD

SOL-1 Clinical Evidence

Dilsher S. Dhoot, MD, FASRS

Key Insights

Adnan Tufail MBBS, MD, FRCOphth

Clinical Program Update

Arshad M. Khanani, MD, MA, FASRS

Panel Discussion

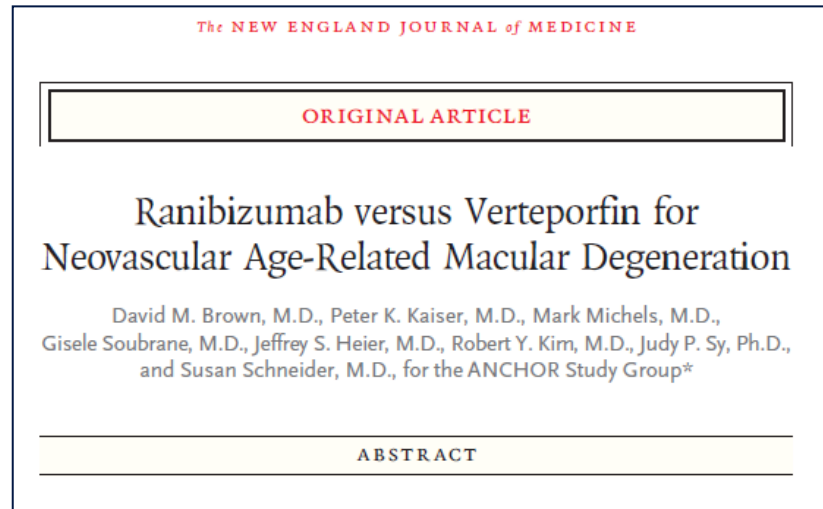
Moderator: Arshad M. Khanani, MD, MA, FASRS

The Unmet Need

Adnan Tufail MBBS, MD, FRCOphth

Anti-VEGF has Transformed Our Management of Neovascular AMD

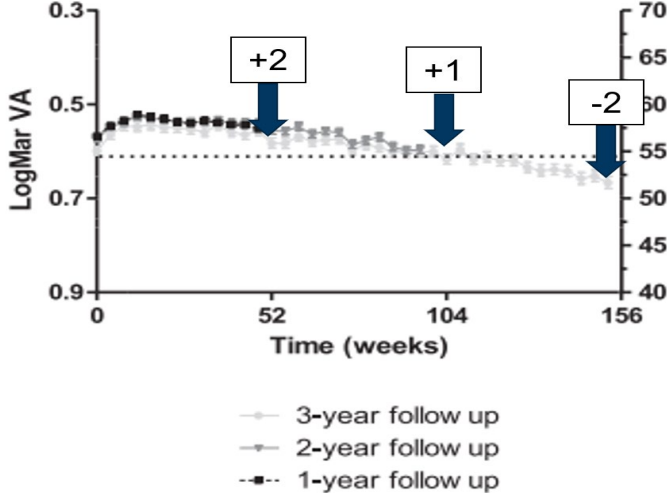
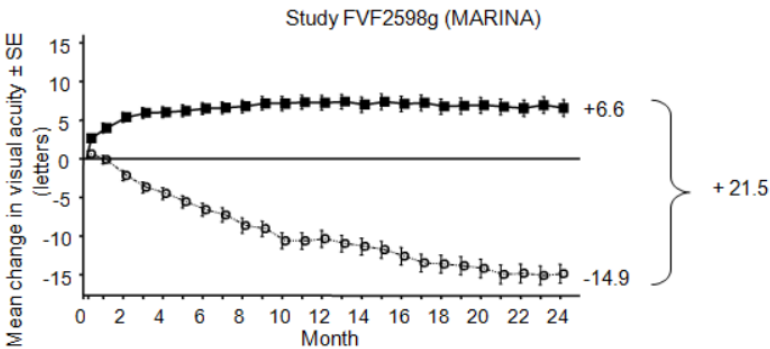
Delivering anti-VEGF in clinical practice and achieving optimal outcomes remain challenging



However, Real World Outcomes Do Not Reflect Clinical Trial Results

Report 1 Ophthalmology 2014

12,951 eyes; 11,135 patients; 92,976 ranibizumab injections. PRN regimen. Mean VA: baseline 55 → yr1 +2 (57) → yr2 +1 (56) → yr3 -2 (53). Median injections: 6/4/4 per year. 90%/84%/82% avoided moderate vision loss.



14

UK NHS centers
contributing data

12,951

Treatment-naive
nAMD eyes

92,976

Ranibizumab injections
analysed

79.7 yrs

Mean patient age
(63% female)

Visual Acuity Outcomes in the Real World

Evidence Base: Pivotal Trials, UK EMR Users Group, FRB & IRIS Registries

Pivotal RCTs

Gold-standard efficacy data

- MARINA/ANCHOR (ranibizumab)^{1,2}
- CATT (ranibizumab vs bevacizumab)³
- VIEW 1 & 2 (aflibercept 2mg)⁴
- HAWK & HARRIER (brolucizumab)⁵
- TENAYA & LUCERNE (faricimab)⁶
- PULSAR (aflibercept 8mg)⁷

UK EMR data

UK EMR. · NOD AMD

- 14 UK NHS centres, Reports 1–4
- 12,951 eyes; 92,976 injections
- Tufail et al. 2014–16 (Ophthalmology)^{8,9}
- PRN: +2 letters yr 1; –2 by yr3
- Schwartz 2021: 27 centers, 10-yr study¹⁰
- NOD AMD Audit: national benchmarks¹¹

FRB Registry

Fight Retinal Blindness! — International

- 150+ practitioners, 20+ countries
- Real-world T&E and PRN outcomes¹²
- 2,000+ nAMD eyes ≥2 years
- European sub-analyses available¹³
- Faricimab switch data 2023–25¹⁴
- 25% high treatment burden at 2 yrs

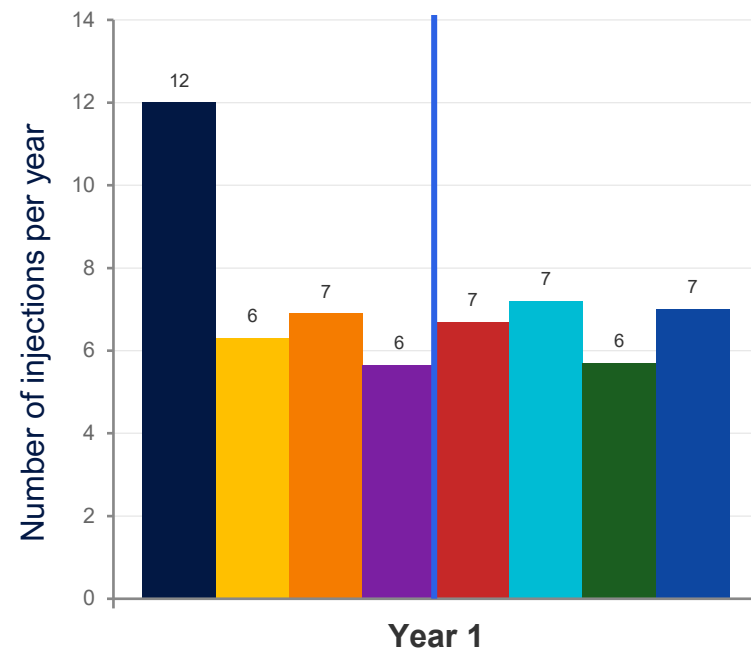
AAO IRIS® Registry

USA National Registry

- 254,655 eyes (226,767 patients)¹⁵
- Up to 6-year longitudinal data
- Anti-VEGF exposure analysis
- 3.7 yrs mean length of follow-up
- 7.2 inj yr 1 → 4.6 inj yr 3
- Real-world injection-VA correlation

Injections per Year: Clinical Trials vs Real-World Practice

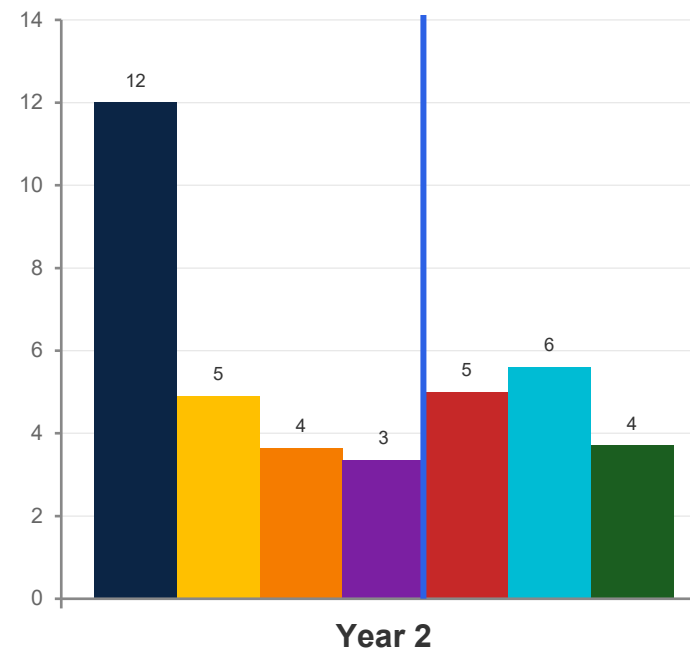
VA Δ +11 +6 +6 +6 +5 +3 +2 +4



■ RCT (monthly fixed)¹
■ FRB Registry (real-world)^{9,10}

■ Brolucizumab (HAWK/HARRIER)²⁻⁴
■ IRIS® Registry (real-world)¹¹

+11 +6 +4 +6 +4 +1 +1



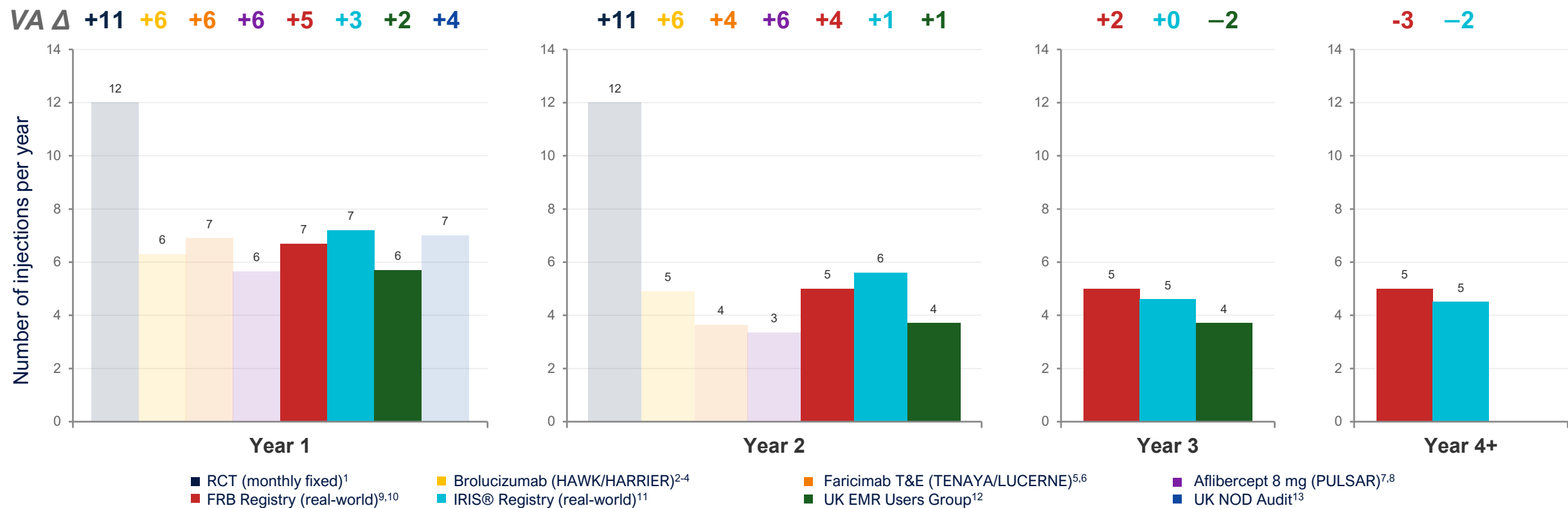
Year 2

■ Faricimab T&E (TENAYA/LUCERNE)^{5,6}
■ UK EMR Users Group¹²

■ Aflibercept 8 mg (PULSAR)^{7,8}
■ UK NOD Audit¹³

Every additional injection in Year 1 was associated with a +0.68 ETDRS letter gain from baseline (IRIS Registry)¹¹
Under-treatment in real-world practice is a major driver of worse outcomes

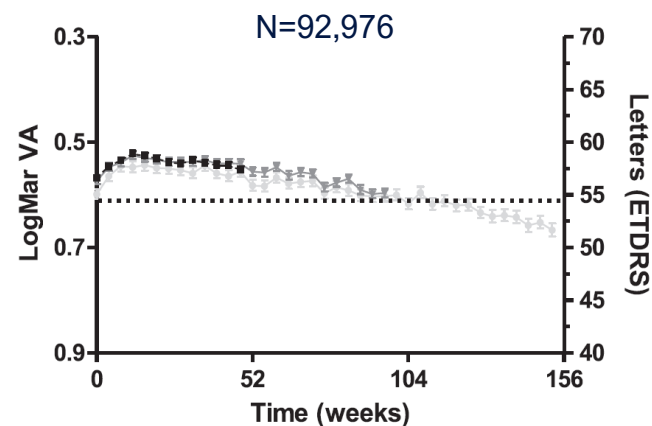
Injections per Year: Clinical Trials vs Real-World Practice



Every additional injection in Year 1 was associated with a +0.68 ETDRS letter gain from baseline (IRIS Registry)¹¹
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Eyes with Excellent Baseline Vision Decline on Average in Real-World Studies

Visual Acuity Over Time

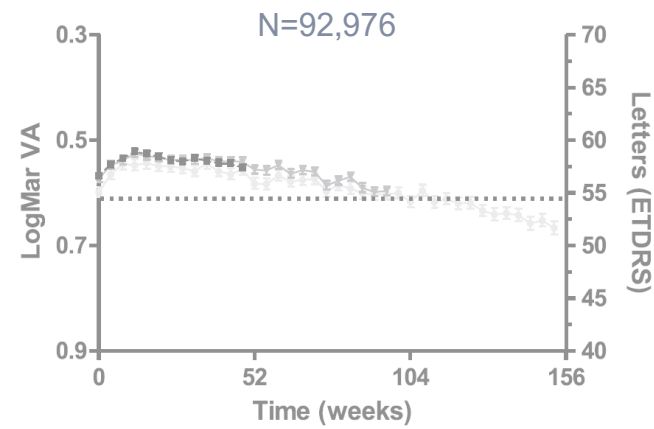


Despite initial gains, **eyes**
showed a sustained decline in
VA over 3 years

—○— 3-year follow up
—■— 2-year follow up
- - - 1-year follow up

Eyes with Excellent Baseline Vision Decline on Average in Real-World Studies

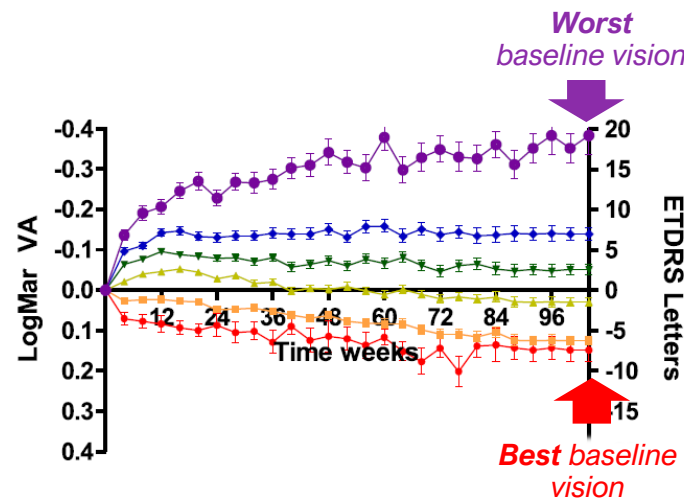
Visual Acuity Over Time



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— 3-year follow up
— 2-year follow up
- - - 1-year follow up

Change in Vision Stratified by Baseline VA

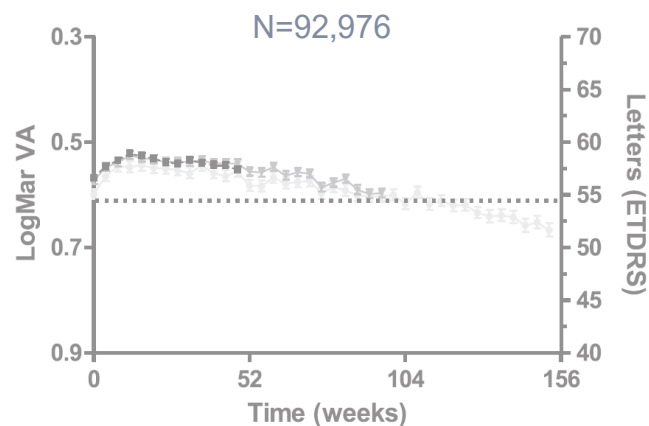


Change in vision is dependent on baseline status with **eyes starting with better vision showing greater decline**

— Baseline -0.29-0.00 (n=166) — Baseline 0.61-0.90 (n=2905)
— Baseline 0.01-0.30 (n=2166) — Baseline 0.91-1.20 (n=1843)
— Baseline 0.31-0.60 (n=3729) — Baseline 1.21-1.50 (n=411)

Actual Visual Acuity, NOT Change, is What is Meaningful to Patients

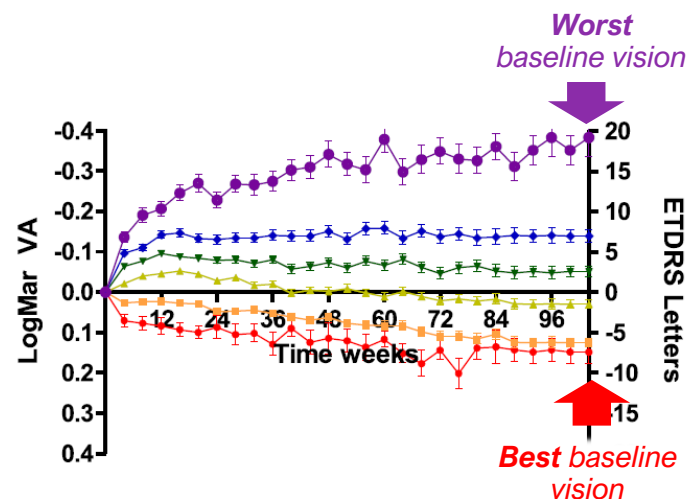
Visual Acuity Over Time



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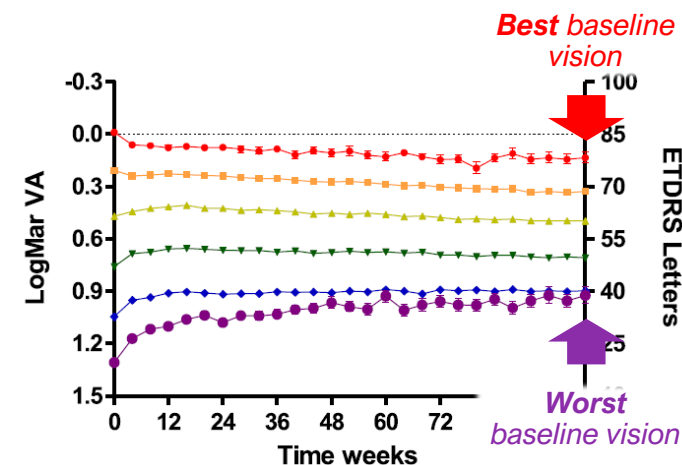
Change in Vision Stratified by Baseline VA



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Mean Vision Stratified by Baseline VA



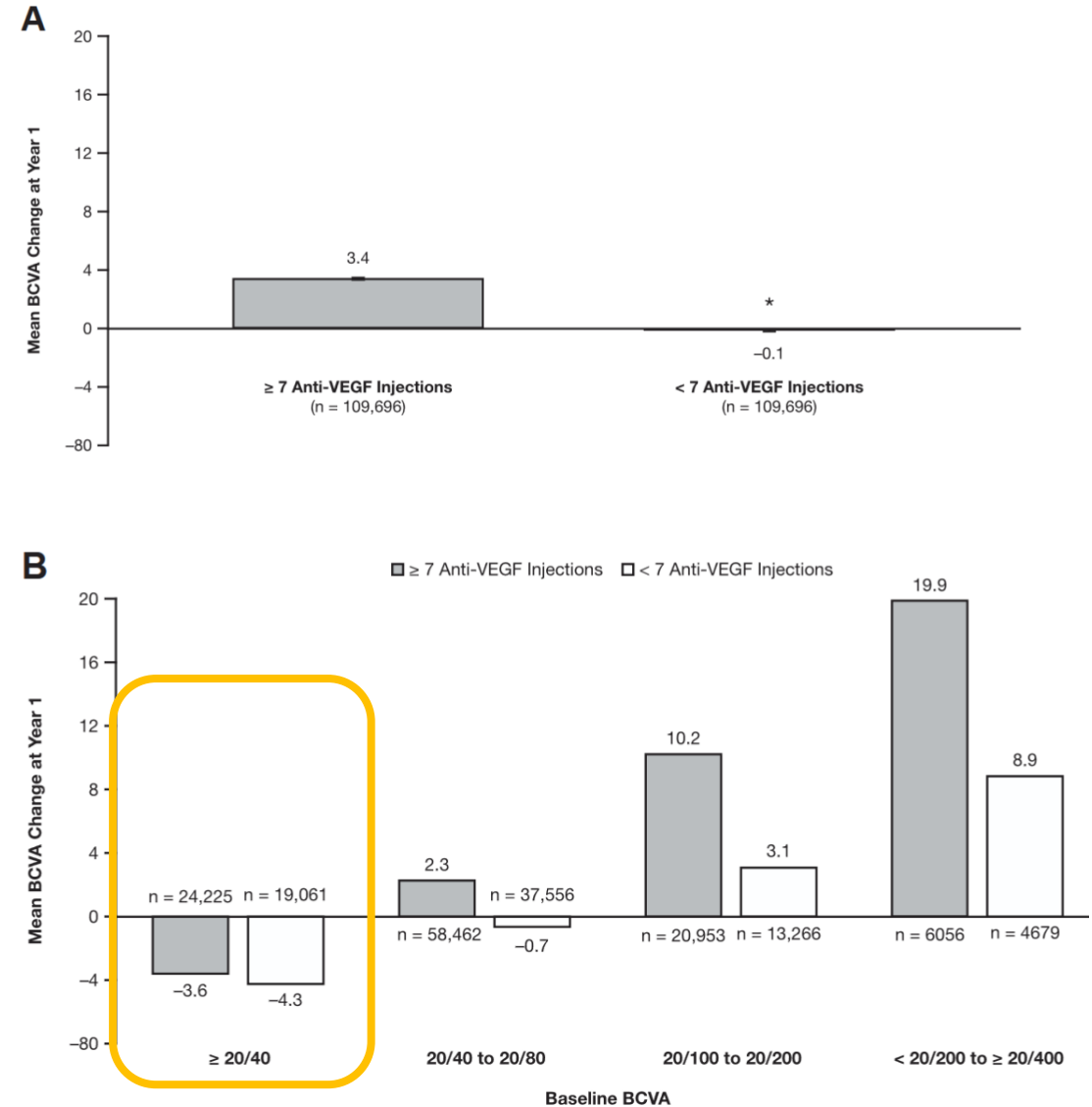
Best baseline vision maintains the highest overall visual acuity

— Baseline -0.29-0.00 (n=166) — Baseline 0.61-0.90 (n=2905)
— Baseline 0.01-0.30 (n=2166) — Baseline 0.91-1.20 (n=1843)
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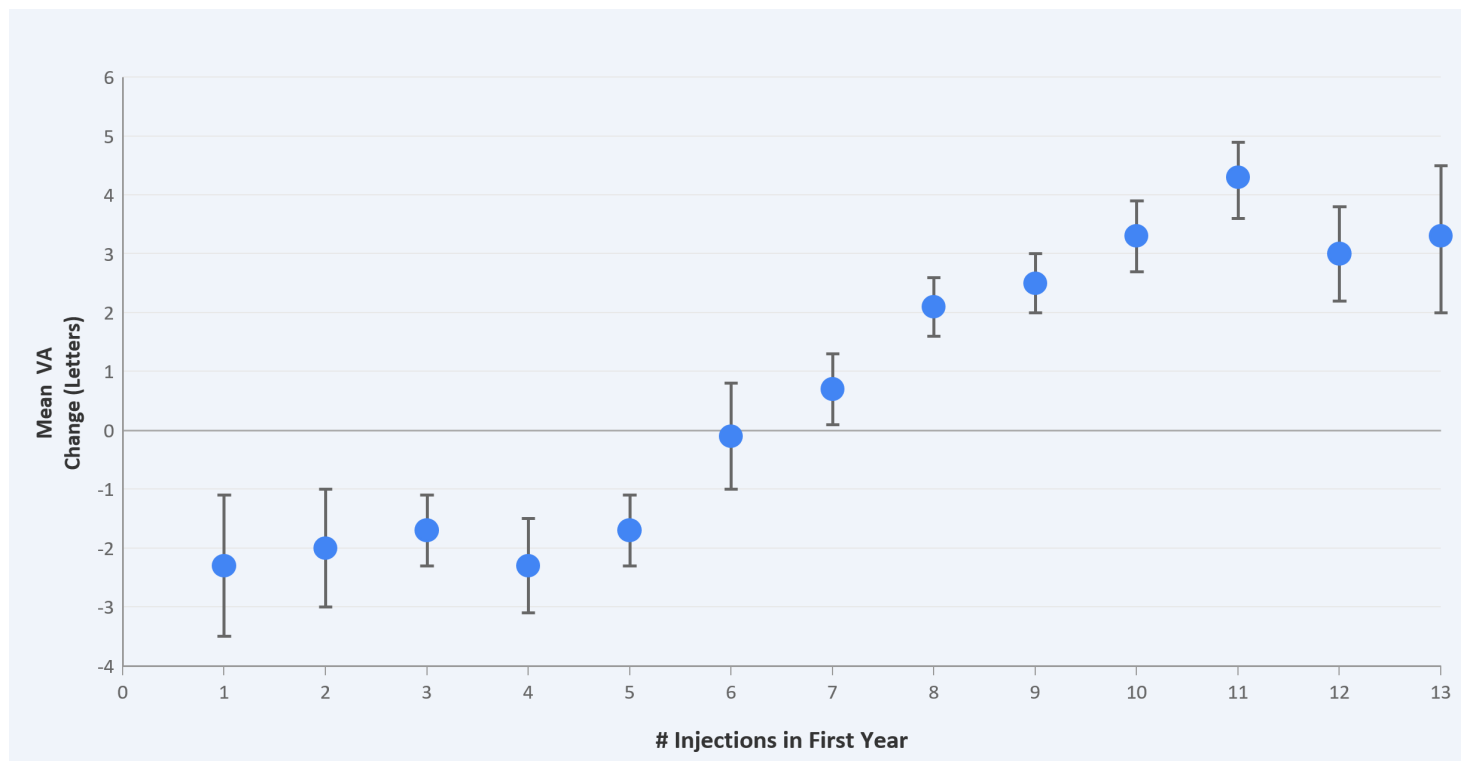
Recent Data Supports Similar Associationⁿ

Characteristics and Outcomes of Patients with Neovascular Age-Related Macular Degeneration by Anti-VEGF Exposure in United States Clinical Practice

- Visual outcomes were evaluated by treatment exposure
 - ≥ 7 or < 7 intravitreal anti-VEGF injections
- 295,561 eligible eyes
 - 184,258 actively treated



The Injection–Outcome Relationship: More Injections = Better Vision



Linear relationship

Between 4–10 injections, each additional injection adds ~0.6 ETDRS letters (n=49,485 eyes)

Under-treatment threshold

≤5 injections associated with mean letter loss.

Ceiling effect

Gains plateau at ≥10 injections — excess treatment without additional benefit beyond this point

Why do Patients Discontinue Anti-VEGF Treatment?

- Multi-centre study of nAMD patients (n=2,302 patients)
 - 655 (28.5%) discontinued intravitreal anti-VEGF therapy
 - Early discontinuers were older and had higher baseline VA

Reported reasons for discontinuation

Patient decision against clinical advice — often driven by perceived treatment burden, anxiety about injections, or difficulty attending appointments

Systemic disease or intercurrent illness — hospitalisation, acute cardiovascular events, falls

Clinical decision — poor prognosis, end-stage disease, or insufficient response

Transfer of care to another clinic

Contributing factors in the nAMD population

Elderly age and frailty

Caregiver availability and fatigue

Multiple hospital appointments for other conditions

Polypharmacy and adverse drug events

Anxiety and psychological distress from repeated intravitreal injections

Transport and mobility limitations

Treatment burden is the common denominator - amplifies every other risk factor for discontinuation in this frail, elderly population

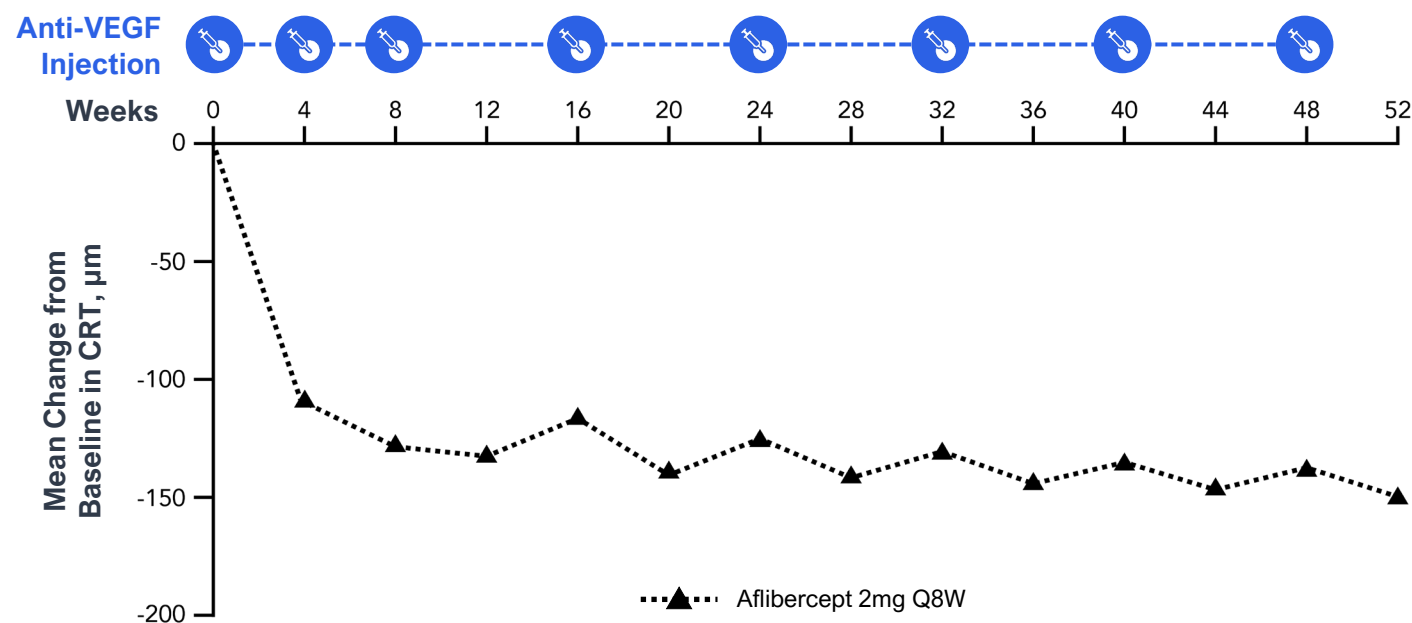
Greater Retinal Thickness Variability During Anti-VEGF Therapy is Associated with Suboptimal Anatomic and Visual Outcomes

Retinal Thickness
Fluctuations

Development of
Fibrosis and Atrophy

Poorer Long-Term
Visual Outcomes

Repeated cycles of fluid resolution and recurrence are reflected in fluctuations in retinal thickness over time



Greater Retinal Thickness Variability During Anti-VEGF Therapy is Associated with Suboptimal Anatomic and Visual Outcomes

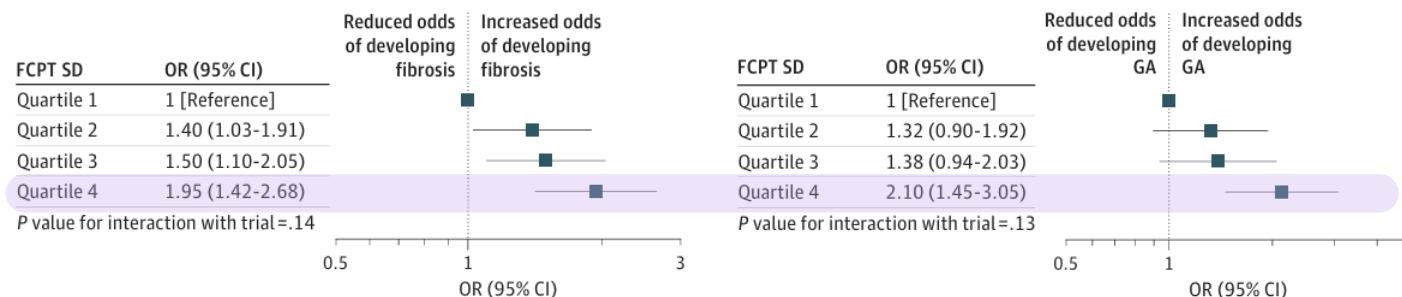
Retinal Thickness
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Poorer Long-Term
Visual Outcomes

JAMA Ophthalmology | Original Investigation

Associations of Variation in Retinal Thickness With Visual Acuity and Anatomic Outcomes in Eyes With Neovascular Age-Related Macular Degeneration Lesions Treated With Anti-Vascular Endothelial Growth Factor Agents



Highest retinal thickness variability had approximately **double the odds** of developing fibrosis/macular atrophy

Greater Retinal Thickness Variability During Anti-VEGF Therapy is Associated with Suboptimal Anatomic and Visual Outcomes

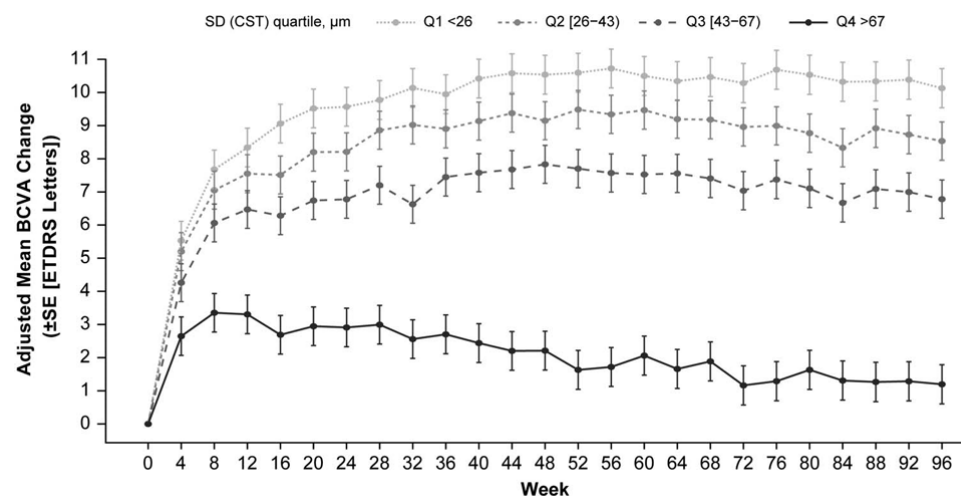
Retinal Thickness
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Visual Outcomes

EFFECT OF RETINAL THICKNESS VARIABILITY ON VISUAL OUTCOMES AND FLUID PERSISTENCE IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

A Post Hoc Analysis of the HAWK and HARRIER Studies

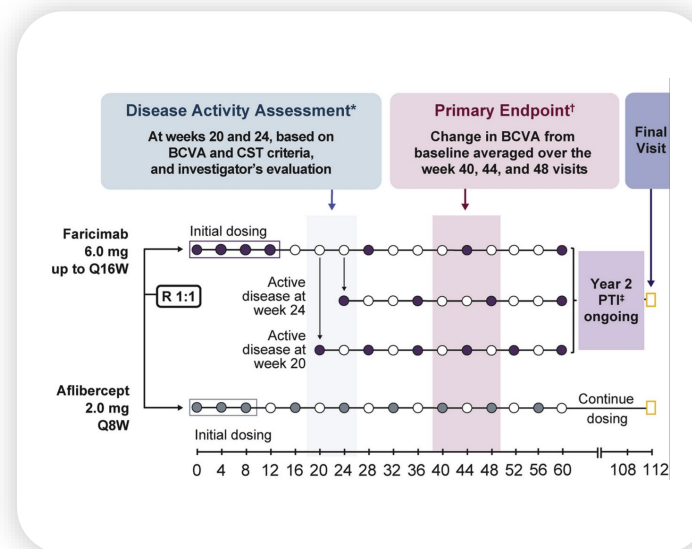


Vision deteriorates
by ~9 letters
between patients
with most and least
stable retinal
thicknesses

Clinical Trials to Real-world Management with New Agents

Limitation of recent clinical trial designs¹

- Clinical trials aimed to get regulatory approval
- Suggest extended interval in subgroups
- Investigational drug subgroup extended but not active control
- Non-inferiority

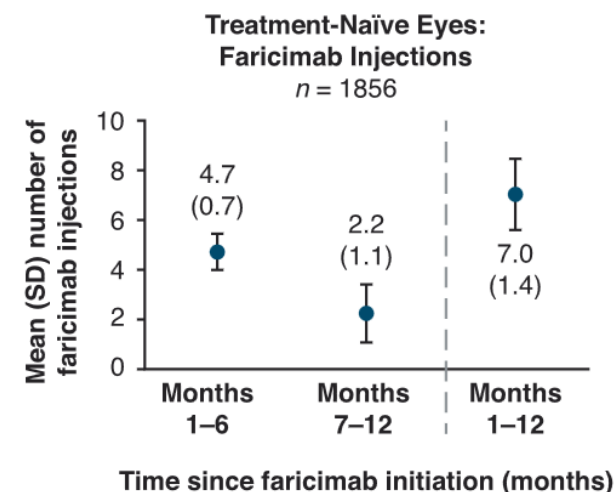
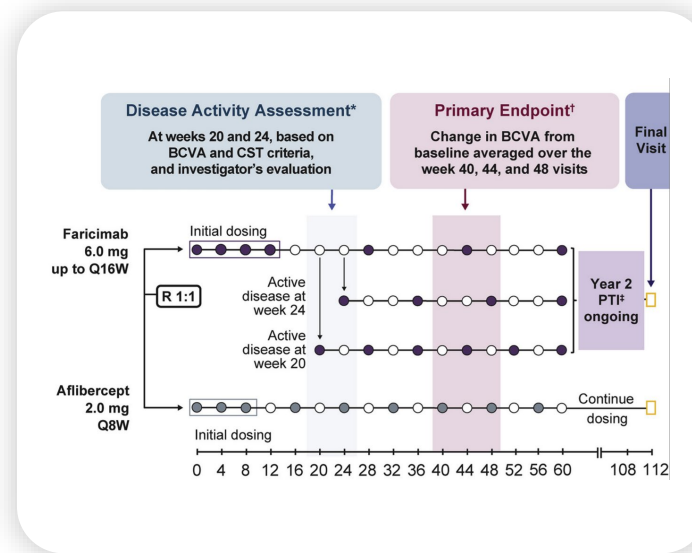


Clinical Trials to Real-world Management with New Agents

Limitation of recent clinical trial designs¹

- Clinical trials aimed to get regulatory approval
- Suggest extended interval in subgroups
- Investigational drug subgroup extended but not active control
- Non-inferiority

Real-world evidence suggests similar VA outcomes with faricimab at 12 months since initiation (mean BCVA gain of 3.6 letters)¹



Summary: Current Status of nAMD Treatment

Real-world outcomes do not match clinical trials
We are not getting much better since their inception

Visual acuity change from baseline dependent on starting acuity

Ideally, more treatment should be given BUT limited by patient/caregiver/healthcare system factors

New agents have not robustly shown superior durability due to clinical trial design limitations, and so far have not translated into significantly superior outcomes

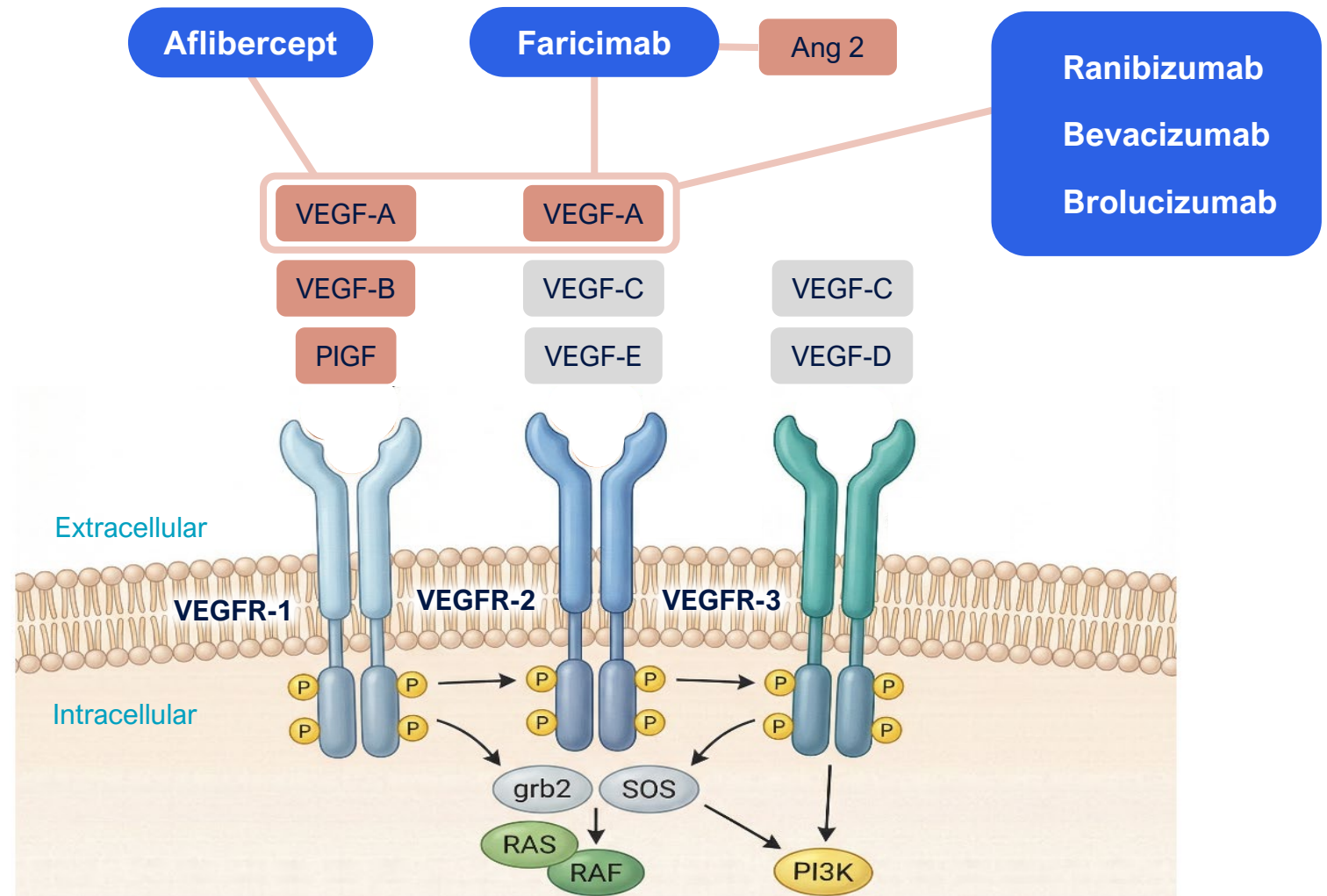
NEED MORE DURABLE THERAPY

Science Behind the Therapy

Dilsher S. Dhoot, MD, FASRS

Current Anti-VEGF Therapies Selectively Target Only Extracellular VEGF

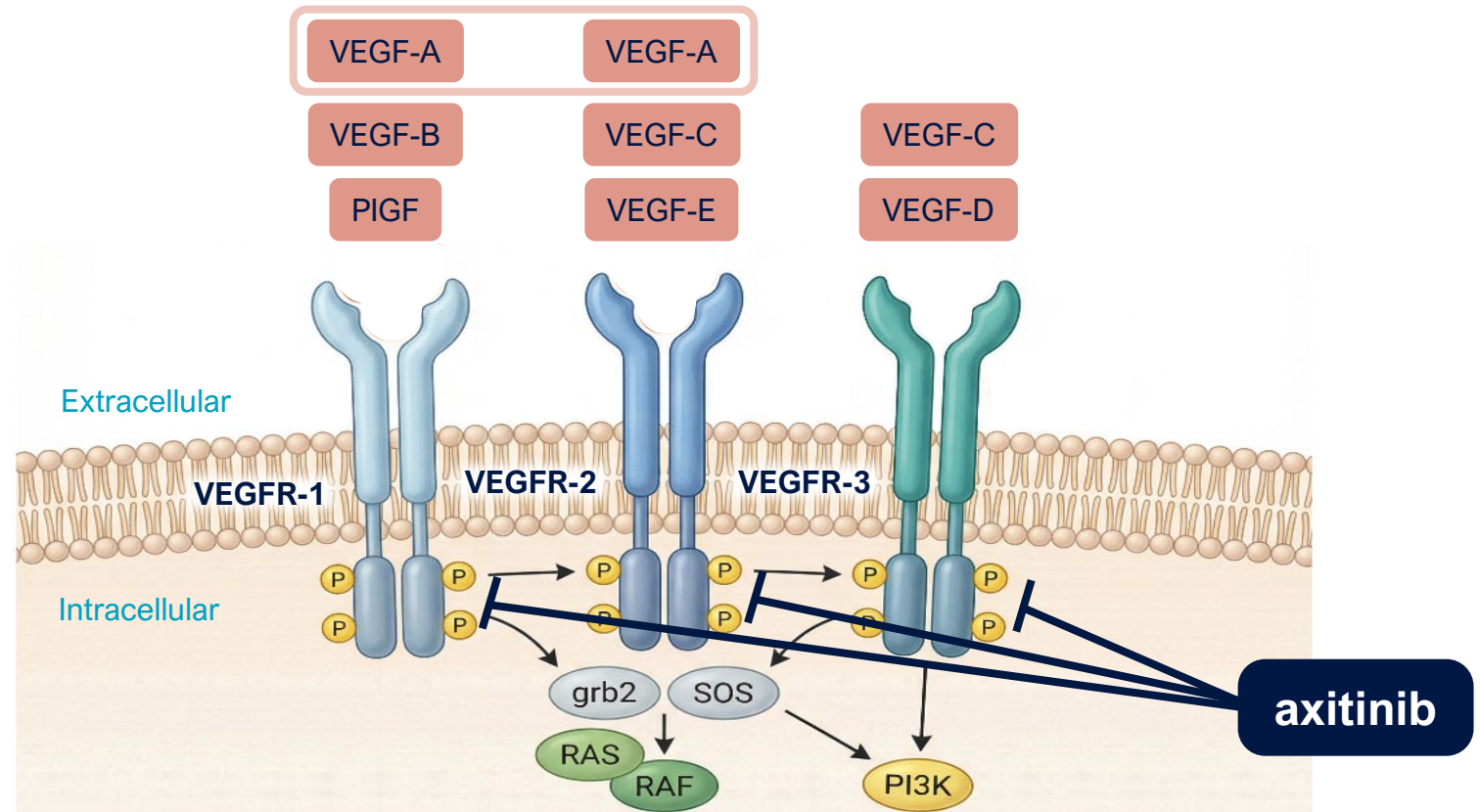
Current **Anti-VEGF** agents act **extracellularly by binding selective ligands**, like VEGF-A, preventing receptor binding and activation^{1,2}



Select extracellular target binding of VEGF, PlGF and Ang-II to inhibit angiogenesis. Adapted from Zhao et al. 2015.^{2,4}

Tyrosine Kinase Inhibitors Act Intracellularly to Inhibit Receptor Signaling

Tyrosine Kinase Inhibitors (TKI) bind at the **intracellular tyrosine kinase domains** of VEGF receptors, inhibiting ATP binding and preventing activation of pro-angiogenic signaling^{1,2}

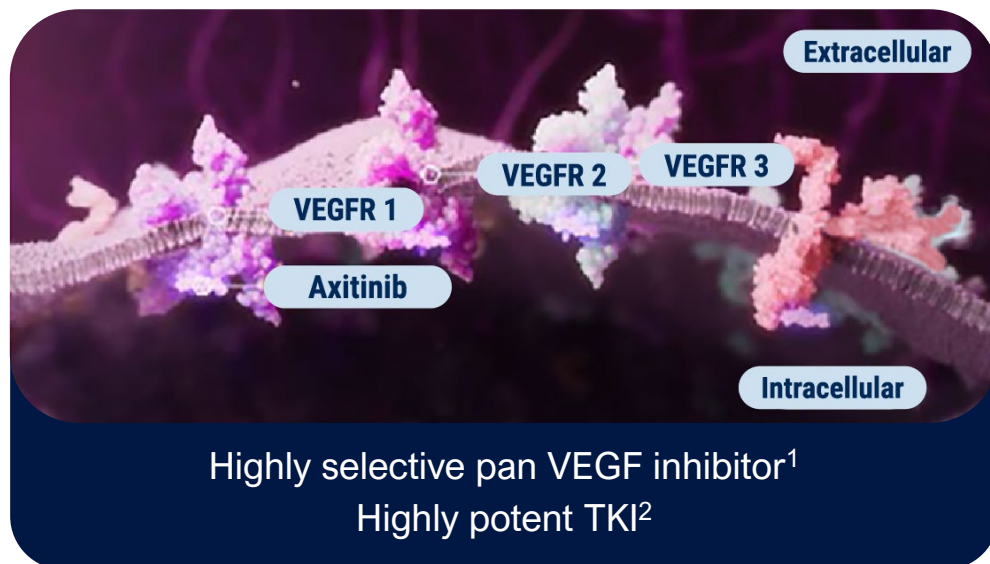


Select angiogenesis intracellular targets of inhibition for tyrosine kinase inhibitors. Adapted from Zhao et al. 2015.^{2,4}

OTX-TKI: Axitinib via Hydrogel Allows for Tunable Sustained Release

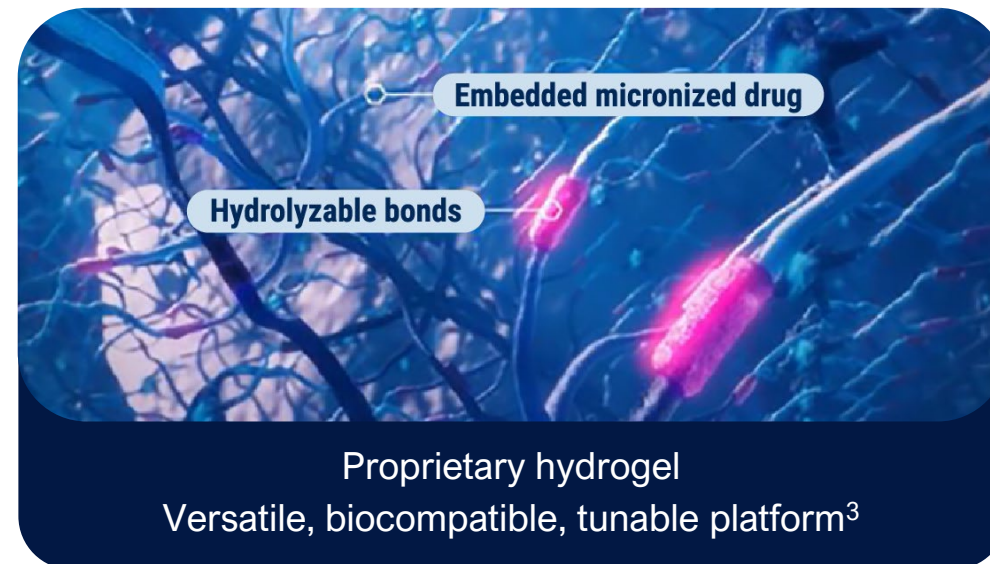
AXITINIB

Multi-target Tyrosine Kinase Inhibitor (TKI)



HYDROGEL TECHNOLOGY

Bioresorbable, Sustained Drug Delivery



+

OTX-TKI

is being developed with the aim to provide:

A single hydrogel insert^{3,4}

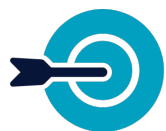
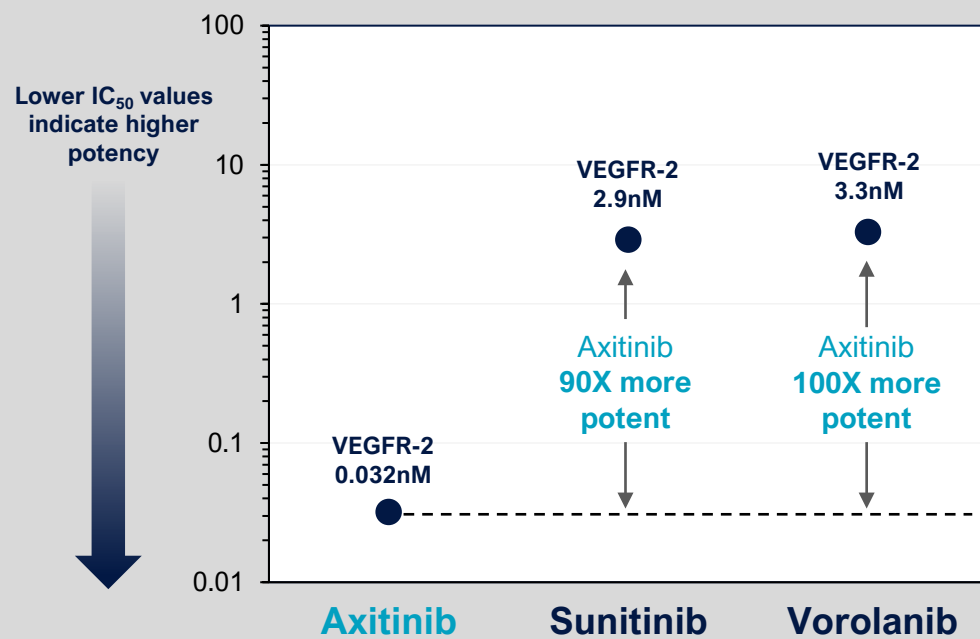
Continuous and consistent delivery up to 12 months^{3,5}

Complete and predictable bioresorption^{3,5}

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

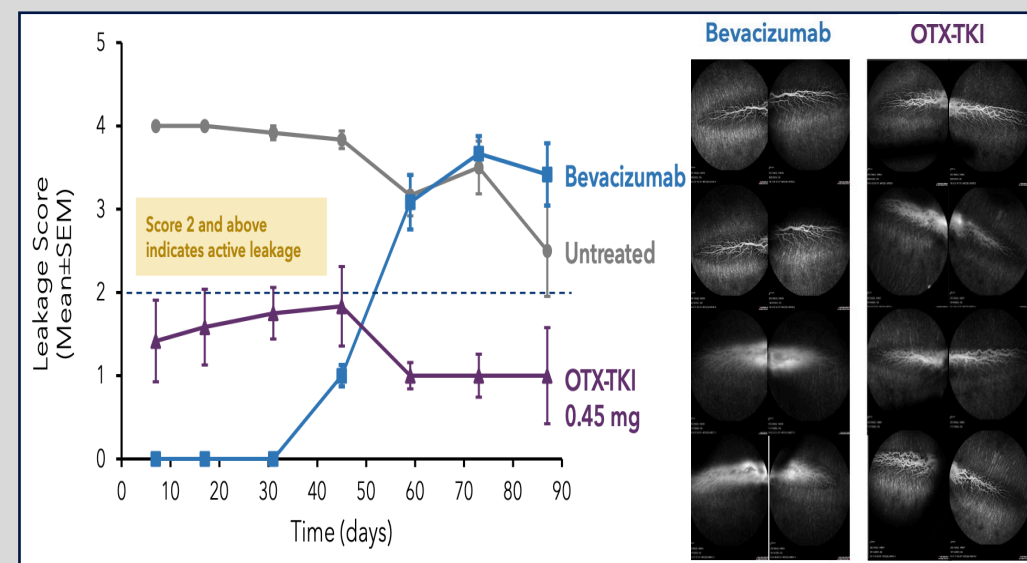
Axitinib: Highly Selective, Very Potent VEGFR Inhibitor

IC₅₀ for VEGF Receptor 2 (nM)¹⁻³



Highly selective for all VEGF receptors, ~100x more potent for VEGFR-2¹⁻³

VEGF Challenge Rabbit Model²



Sustained leakage control in repeat VEGF challenge animal model²

Axitinib demonstrates strongest inhibition of all VEGF/PDGF/FGF Receptors

AssayQuant (Fluorescence Assay)*

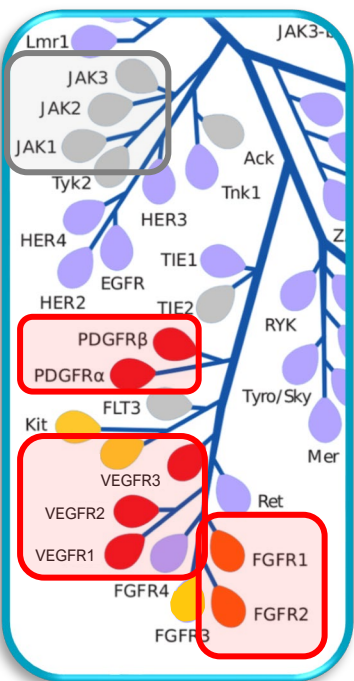
1µM Axitinib*

1 mM ATP

Physiologic Testing Conditions

1µM*

Axitinib intraocular conc = 1.03 to 1.13 µM
Vorolanib intraocular conc = 0.23 to 0.95 µM^{3,4,6}



Kinase ^{1,2}	Axitinib	Vorolanib ³⁻⁵	Sunitinib
VEGF RECEPTORS			
VEGFR1	99%	39%	83%
VEGFR2	97%	28%	71%
VEGFR3	95%	59%	72%
OTHER RECEPTORS			
PDGFRα	79%	42%	70%
PDGFRβ	88%	41%	87%
FGFR1	76%	0%	45%
FGFR2	76%	16%	54%
FGFR3	67%	15%	63%
JAK1	18%	21%	52%

Reaction Biology (Radiometric Assay)**

1 mM ATP

Physiologic Testing Conditions

1µM*

Axitinib intraocular conc = 1.03 to 1.13 µM
Vorolanib intraocular conc = 0.23 to 0.95 µM^{3,4,6}

Kinase ^{1,2}	Axitinib	Vorolanib ³⁻⁵	Sunitinib
VEGF RECEPTORS			
VEGFR1	72%	6%	12%
VEGFR2	76%	6%	14%
VEGFR3	63%	27%	18%
OTHER RECEPTORS			
PDGFRα	54%	37%	37%
PDGFRβ	79%	75%	76%
FGFR1	69%	12%	28%
FGFR2	62%	17%	28%
FGFR3	87%	40%	58%
JAK1	5%	14%	0%

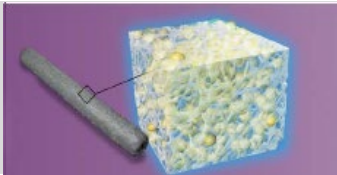
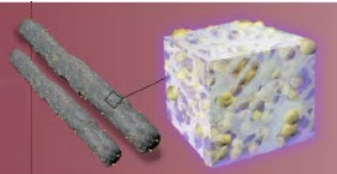
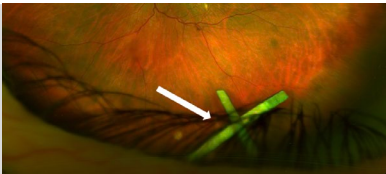
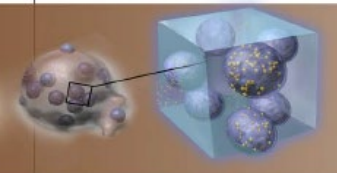
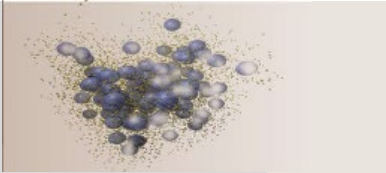
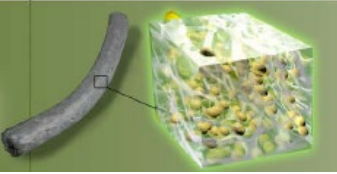
Inhibition Key: <50% 50-70% 70-85% 85-100% Not tested



Retina
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redefined™

*Kinome Tree inhibition analysis conducted in collaboration with AssayQuant. PhosphoSens® assay (AssayQuant®) conducted at 1mM ATP and 1µM drug concentrations. **Reaction Biology HotSpot kinase screening (Radiometric Assay) conducted at 1mM ATP and 1µM drug concentrations. 1. Data on file, Ocular Therapeutix. 2. Patel C, et al. Target and Selectivity Profiling of Axitinib in Cell-Based and Biochemical Assays. Presented at the Association for Research in Vision and Ophthalmology. May 8, 2025, Salt Lake City, UT. 3. Singh RP, et al. A 12-Month, Ocular Pharmacokinetic Study of EYP-1901, a Sustained-release, Intravitreal Formulation of the Tyrosine Kinase Inhibitor Vorolanib. Presented at the American Society of Retina Specialists Annual Meeting; July 28–August 1, 2023; Seattle, WA; 4. Kupperman BD, et al. Poster B0301. Presented at ARVO 2024 Annual Meeting, May 5–9, 2024; Seattle, WA; 5. Xiu X, et al. *Organic Process Research & Development*. 2024;28(2):492-499; 6. Saim, S., Howard-Sparks, M., Paggiarino, D., Karzoun, B. and Chen, J., Eyepoint Pharmaceuticals Inc, 2026. Bioerodible ocular drug delivery insert and therapeutic method. U.S. Patent 12,551,368; TKI, tyrosine kinase inhibitor; ATP, adenosine triphosphate; VEGFR, vascular endothelial growth factor receptor; PDGFR, platelet-derived growth factor receptor; FGFR, fibroblast growth factor receptor; JAK, janus kinase. TIE2, tyrosine kinase with immunoglobulin-like and epidermal growth factor-like domains-2.

Comparison of Hydrogel vs Other Retinal Polymer Implants

	Implant (Full View)	Implant Dimensions (Length x Diameter)	Needle Size	Matrix Degradation & Release ^{^^}	Polymer Byproduct	Implant Remnants at 12 Months
OZURDEX abbvie		6mm x 0.46mm* 	22-gauge*		Lactic acid and glycolic acid [†]	Remnant lasts ~12 months [‡]
EYP-1901 EYEPOINT [™] PHARMACEUTICALS		Two implants with length of 6mm each [¶] 	22-gauge [#]		>75 KDa polyvinyl alcohol	Two remnants last 18-24 months ^{**}
GB-102 graybug vibrant vision		N/A	27-gauge ^{††}		Lactic acid and glycolic acid ^{††}	N/A
OTX-TKI OCULAR THERAPEUTIX		7mm x 0.40mm [^] 	25-gauge [^]		Inert hydrogel PEG chains [^]	No remnants^{^^}

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

Schematic drawings, not drawn to scale or color, for illustrative purposes only; yellow or gray dots/spheres depict therapeutic agents released by implants. Images of EYP-1901 implants from Abbey, AM. Topline Data from DAVIO 2: a Phase 2 Study of a Single Injection of DURAVYU (Vorolanib Intravitreal Insert). Presented at Retina World Congress. Fort Lauderdale, FL; May 9-12, 2024.

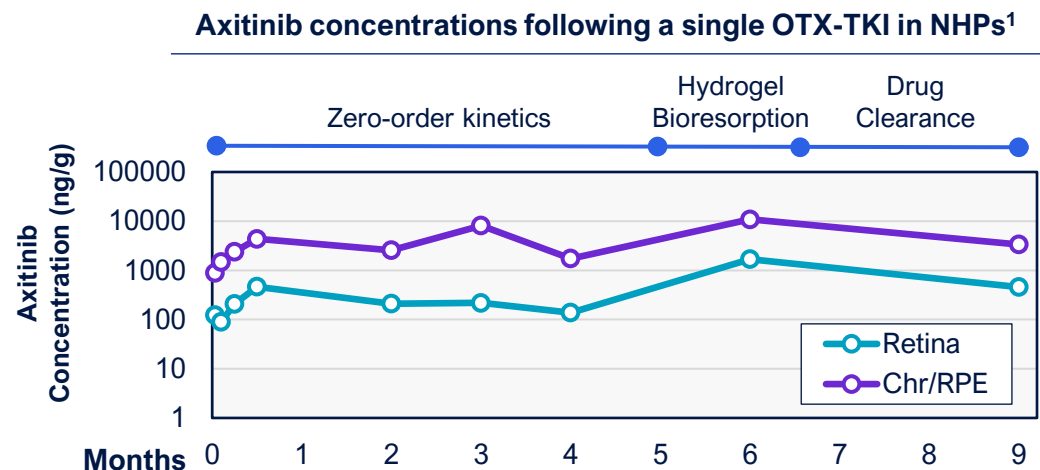
*. Li M, et al. *Heliyon*. 2022;8(12):e12219. †. Pellegrini GABP, et al. *Int J Retina Vitreous*. 2025;11(1):7. ‡. Kim JT, et al. *Retina*. 2020; 40(11):p 2226-2231. §. Schmit-Eilenberger VK. *Clin Ophthalmol*. 2015;9:801-811. ¶. Diameter of EYP-1901 unconfirmed; EyePoint Pharmaceuticals. Clinical Study Protocol. Protocol No. EYP-1901-201. Published January 25, 2024. ClinicalTrials.gov identifier: NCT05381948.. #. EyePoint Pharmaceuticals DAVIO2 Topline Results Conference Call, December 4, 2023. ||. Wykoff CC, et al. *J Vitreoretin Dis*. 2024;8(5):577-586. **EyePoint Pharmaceuticals. TD Cowen 44th Annual Health Care Conference. March 5, 2024. <https://investors.eyepointpharma.com/events-and-presentations>. ††. Graybug Vision Inc. Clinical Study Protocol. Protocol No. GBV-102-002. Published September 8, 2020. ClinicalTrials.gov identifier: NCT03953079. ^. Blizzard CD, et al. Ocular Implant Containing a Tyrosine Kinase Inhibitor. US Patent 11,439,592 B2. September 13, 2022. ^^ Data on File 044. Ocular Therapeutix. 2026. PEG, polyethylene glycol

OTX-TKI is Designed to Release Axitinib and Maintain Intraocular Drug Levels Over Time

OTX-TKI In Vivo Delivery Profile¹

Rapid, continuous and consistent axitinib delivery

Targeted drug delivery to retina and choroid

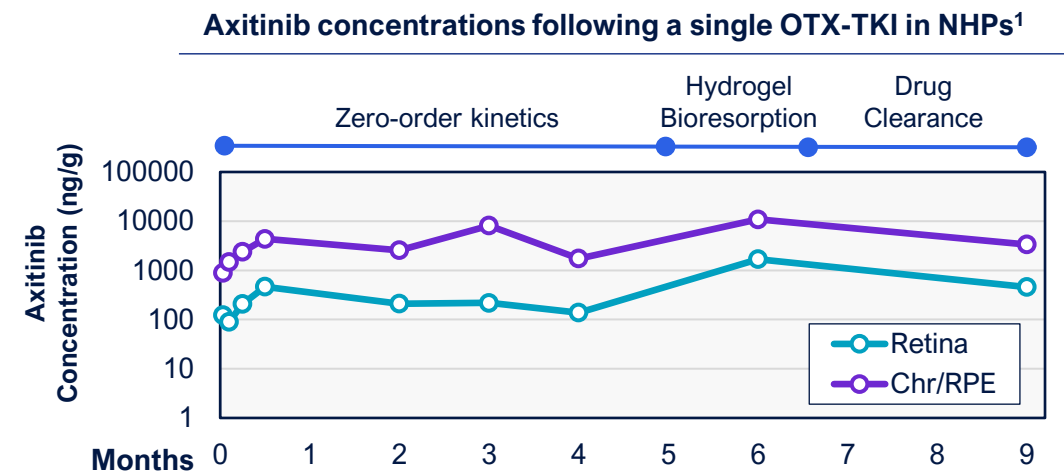


OTX-TKI is Designed to Release Axitinib and Maintain Intraocular Drug Levels Over Time with Complete Bioresorption

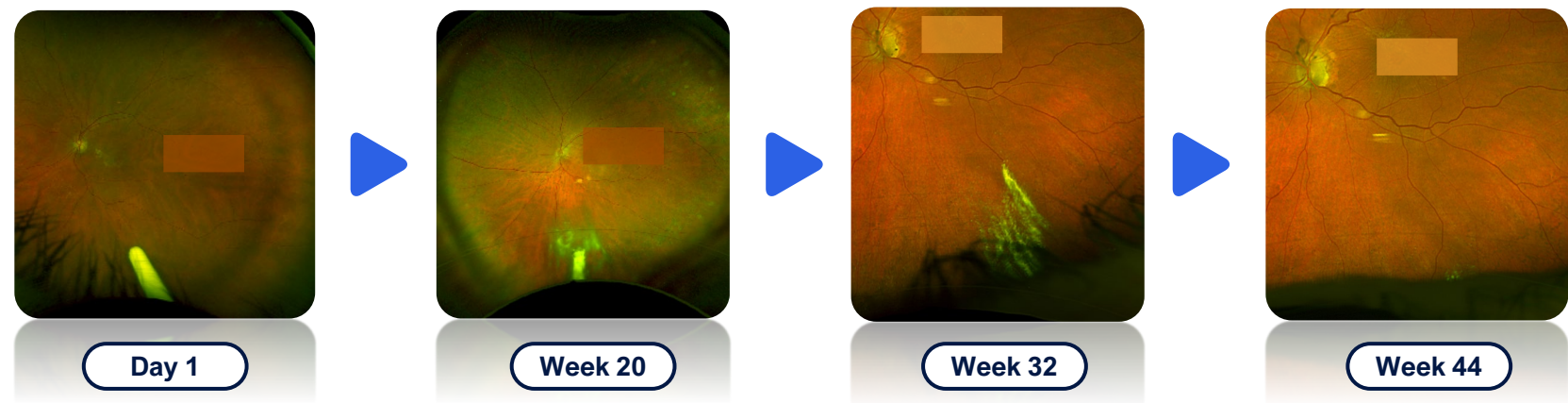
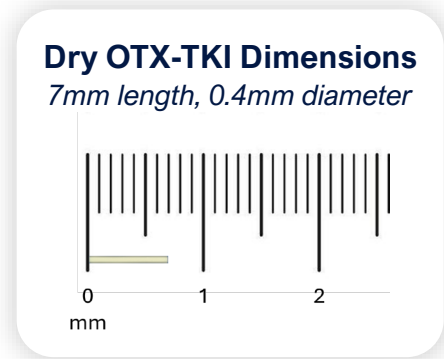
OTX-TKI In Vivo Delivery Profile¹

Rapid, continuous and consistent axitinib delivery

Targeted drug delivery to retina and choroid

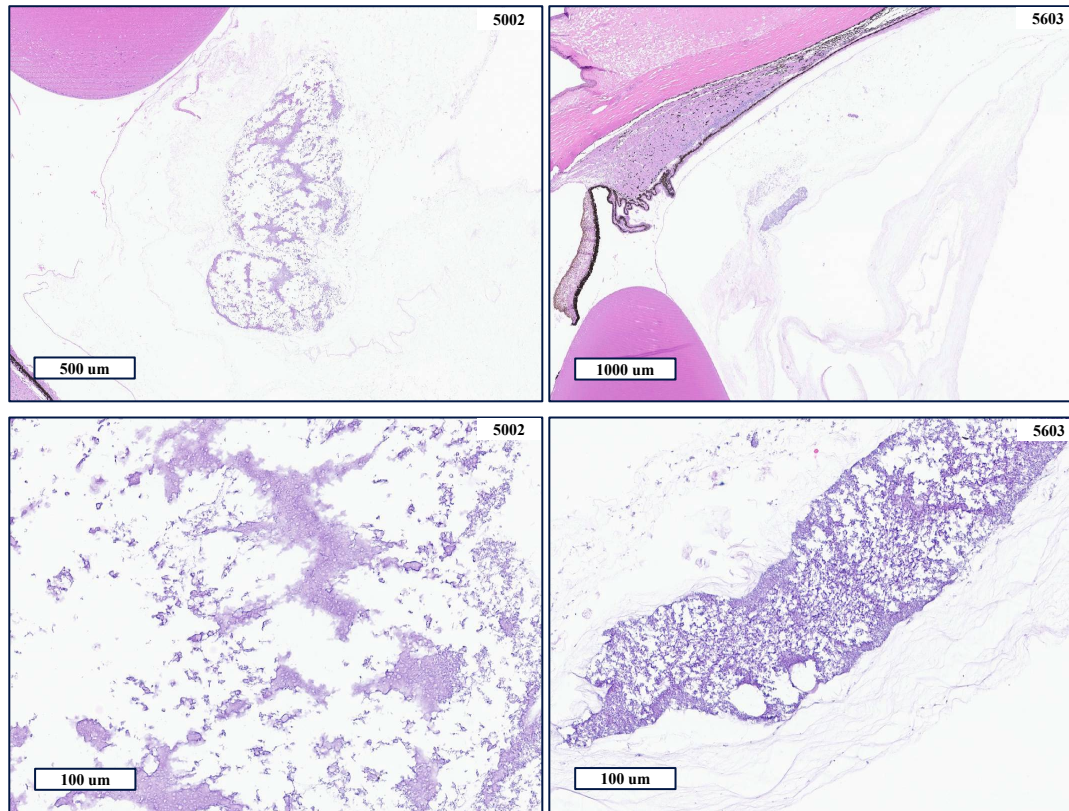


Hydrogel bioresorbs completely and predictably via hydrolysis for potential redosing¹⁻³



Histology of Ocular Tissues Demonstrates Axitinib Elution with No Inflammatory Cells

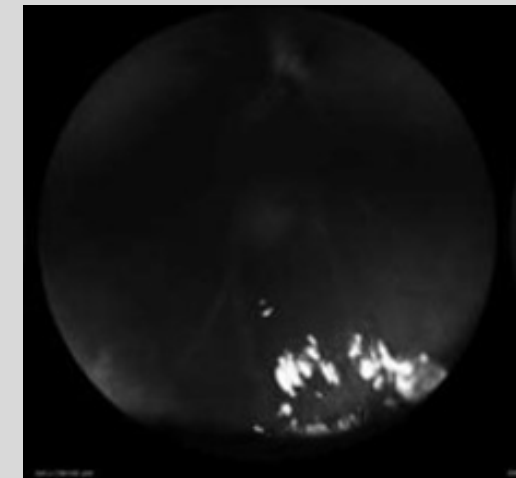
Histology of Ocular Tissues from 0.7 mg OTX-TKI in NHPs



Microscopic Findings

White, refractile, basophilic, granular axitinib in the vitreous

No inflammatory cells in vitreous, retina, or AC



From NHP Toxicity Study, not human picture

OTX-TKI is Designed for Seamless, Immediate Adoption

Ideal Target Product Profile

Pan-VEGF and PDGF
inhibitory activity¹

Axitinib has best-in-class
(TKI) potency¹

Extended durability
up to 12 months²

Single Bioresorbable Hydrogel

No remnants³

Tunable hydrogel⁴

Hydrogel used
in over 5 million patients⁵

Optimizing for Retina Practices

Familiar IVT
injection with **25g needle**⁶

Predictable
schedule for patients²

Designed for **improved**
treatment adherence²

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

SOL-1: Trial Design and Baseline Characteristics

Arshad M. Khanani, MD, MA, FASRS

SOL: OTX-TKI Phase 3 Clinical Program in nAMD

Evaluating the efficacy, durability and safety of OTX-TKI in nAMD

Registrational Trials

SOL-1

Phase 3 Superiority Trial

Durability of a single
OTX-TKI injection

SOL-R

Phase 3 Non-Inferiority Trial

Repeat dosing
every 6 months

Complementary studies designed to
provide a comprehensive characterization of
OTX-TKI across patient populations

Extension Study

SOL-X

Open-Label Extension

Long-term safety and disease
modifying potential of continuous
VEGF suppression

Eligible patients who
complete end of Year 2 visit
in SOL-1 or SOL-R

SOL: OTX-TKI Phase 3 Clinical Program in nAMD

Evaluating the efficacy, durability and safety of OTX-TKI in nAMD

Registration Trials

SOL-1

Phase 3 Superiority Trial

Durability of a single
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SOL-R

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Repeat dosing
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Extension Study

SOL-X

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Eligible patients who
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in SOL-1 or SOL-R

Complementary studies designed to
provide a comprehensive characterization of
OTX-TKI across patient populations

OTX-TKI Evaluated in a Superiority nAMD Trial Designed to Align with FDA Guidance

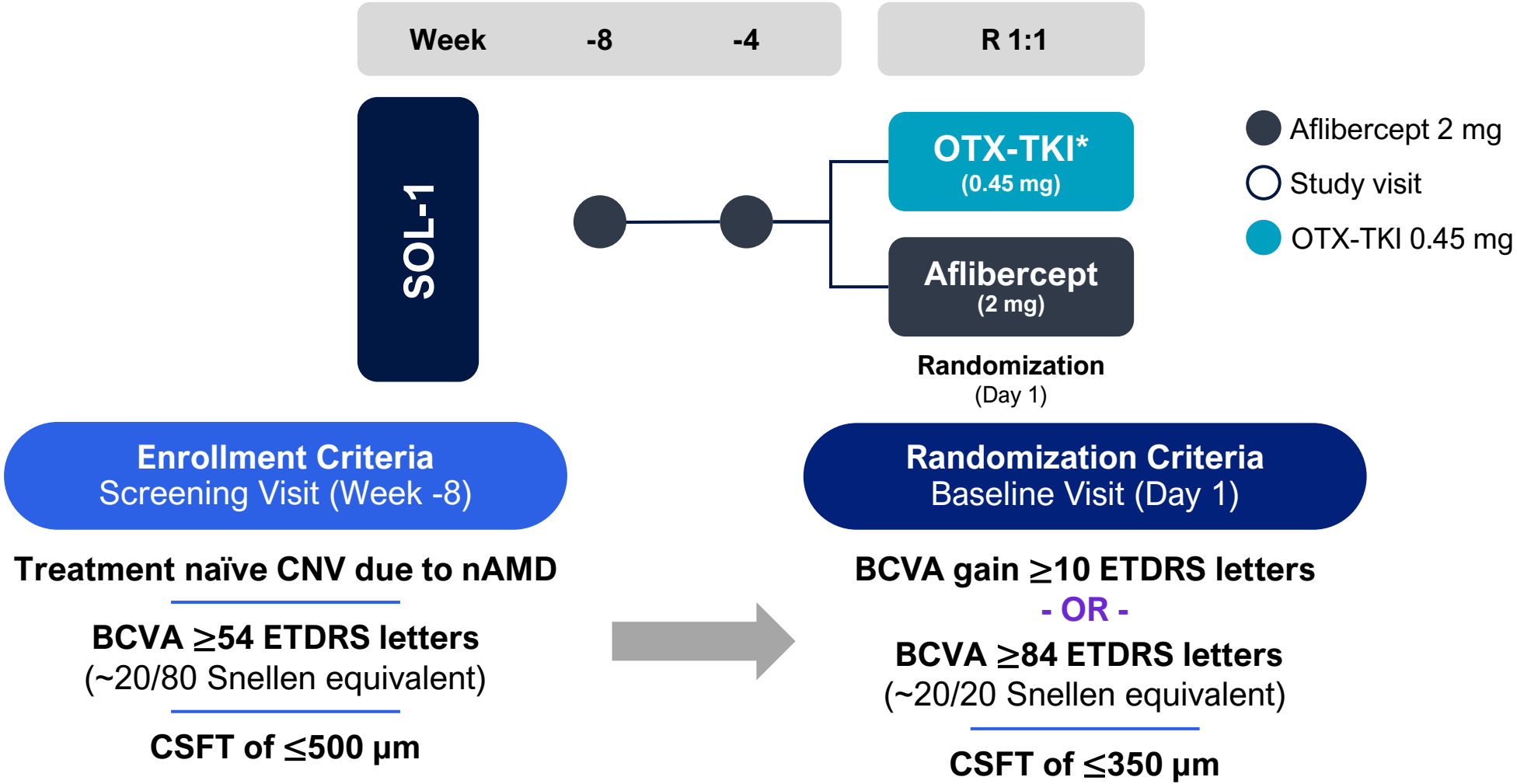
	FDA Guidance for nAMD Trials		SOL-1 Trial Design
Dosing Schedule	One comparator arm should have the same dosing schedule as the investigational drug ¹	✓	Both study arms have same dosing schedule
Sham Injections	Sham injections are not recommended; considered inadequate masking ^{2,3}	✓	No sham injections
Superiority Endpoint	Decrease  ≥15-Letter ¹ Increase  Difference	✓	≥15-Letter Decrease Proportion with <15 ETDRS letters of BCVA loss from baseline at Week 36



- Compares a single OTX-TKI (0.45 mg) dose to a single aflibercept (2 mg) dose
- Designed to show superiority on efficacy and durability
- SOL-1 is being conducted under a **Special Protocol Assessment**

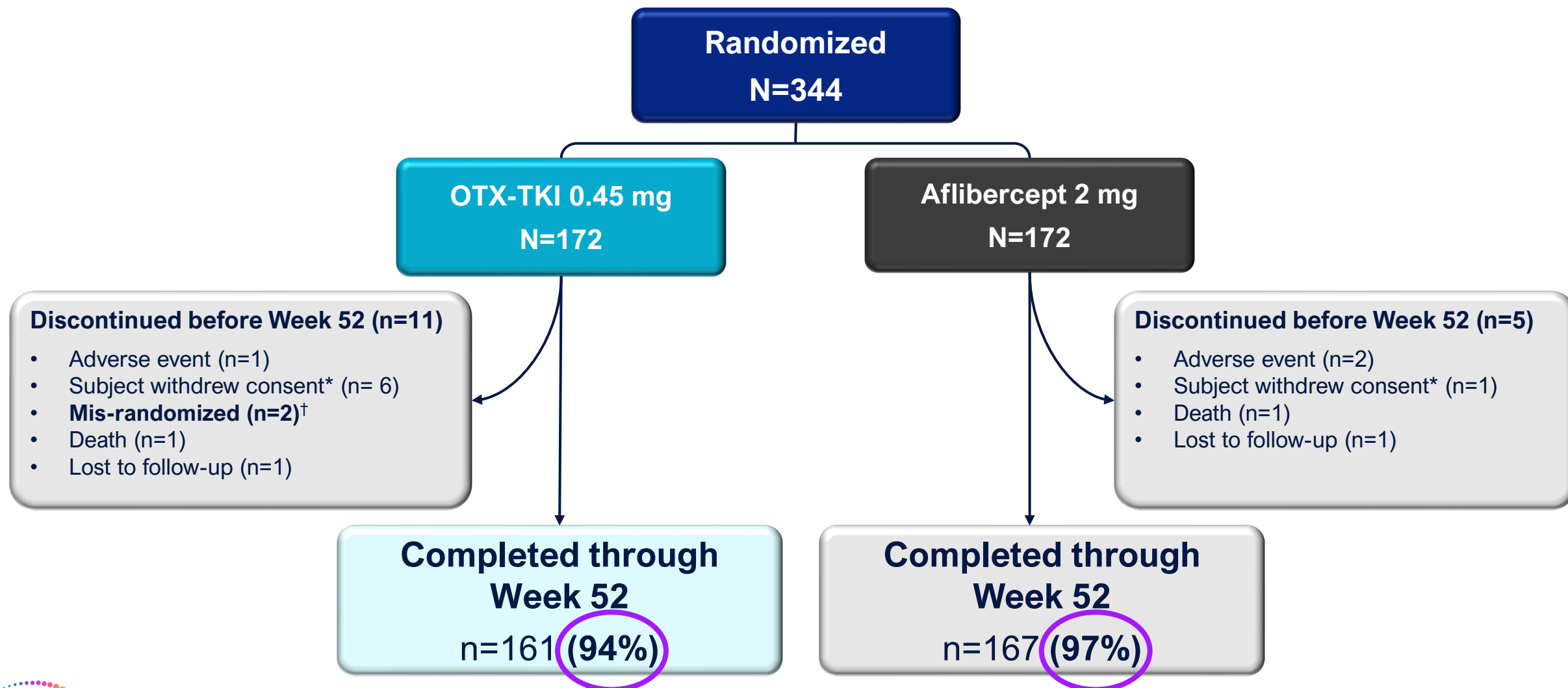
Eligibility and Enrollment Criteria

Key Inclusion Criteria



Strong Subject Retention Maintained through Week 52

Subject Disposition



Excellent Vision at Baseline; Majority Demonstrated ≥ 10 -letter Gain from Screening

SOL-1

Best-Corrected Visual Acuity

Screening Visit (*Week -8*)

Study Eye Characteristics	OTX-TKI 0.45 mg N = 172	Aflibercept 2 mg N = 172
BCVA, ETDRS letter score, mean (SD) Snellen Equivalent	70.9 (11.3) ~20/40	69.5 (10.8) ~20/40

Baseline (*Randomization*)

Study Eye Characteristics	OTX-TKI 0.45 mg N = 172	Aflibercept 2 mg N = 172
BCVA, ETDRS letter score, mean (SD) Snellen Equivalent	80.8 (7.6) ~20/25	79.2 (7.9) ~20/25
Change from Screening to Baseline, n (%)		
≥ 10 ETDRS letter gain	107 (62.9)	114 (67.1)
≥ 84 ETDRS letters (~20/20)	63 (37.1)	56 (32.9)

Anatomic Improvement Observed After Two Aflibercept Injections

Central Subfield Thickness

Screening Visit (Week -8)

Study Eye Characteristics	OTX-TKI 0.45 mg N = 172	Aflibercept 2 mg N = 172
BCVA, ETDRS letter score, mean (SD) Snellen Equivalent	70.9 (11.3) ~20/40	69.5 (10.8) ~20/40
CSFT, μm , mean (SD)	303.6 (72.5)	302.7 (78.3)

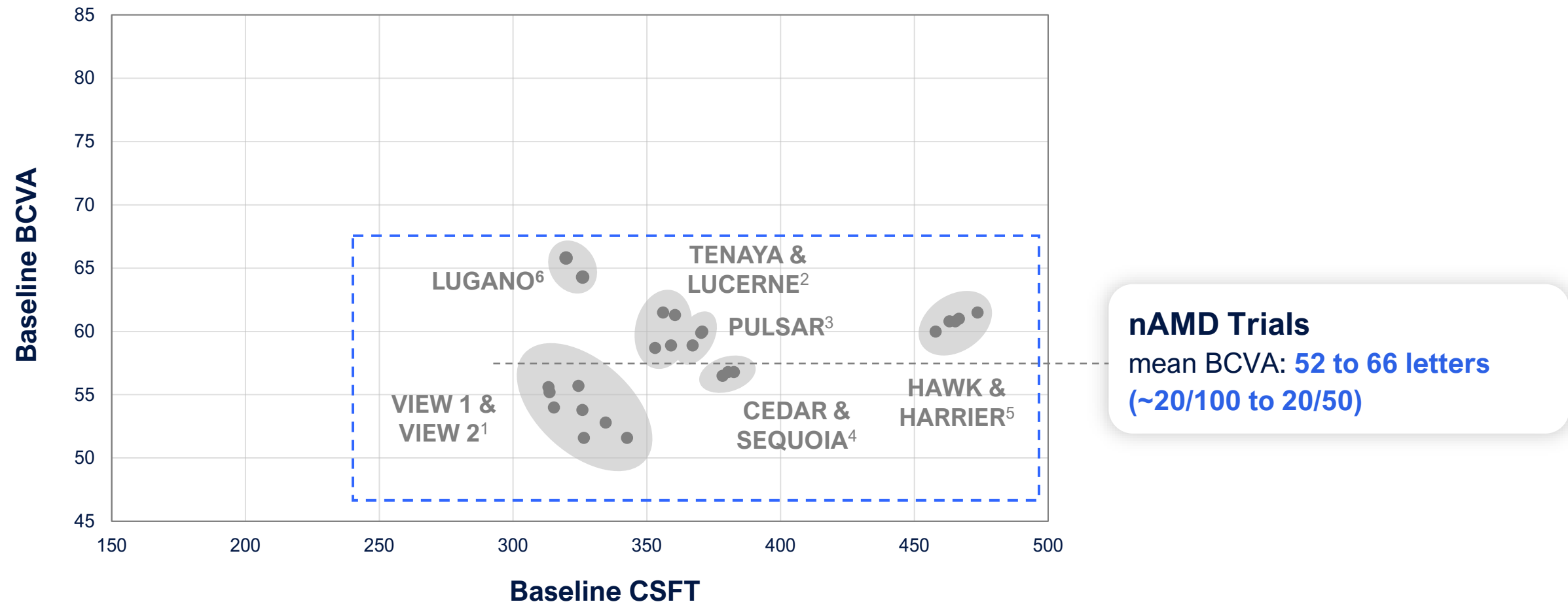
Baseline (Randomization)

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

SOL-1 Evaluated a Distinct nAMD Cohort with Excellent Baseline Vision



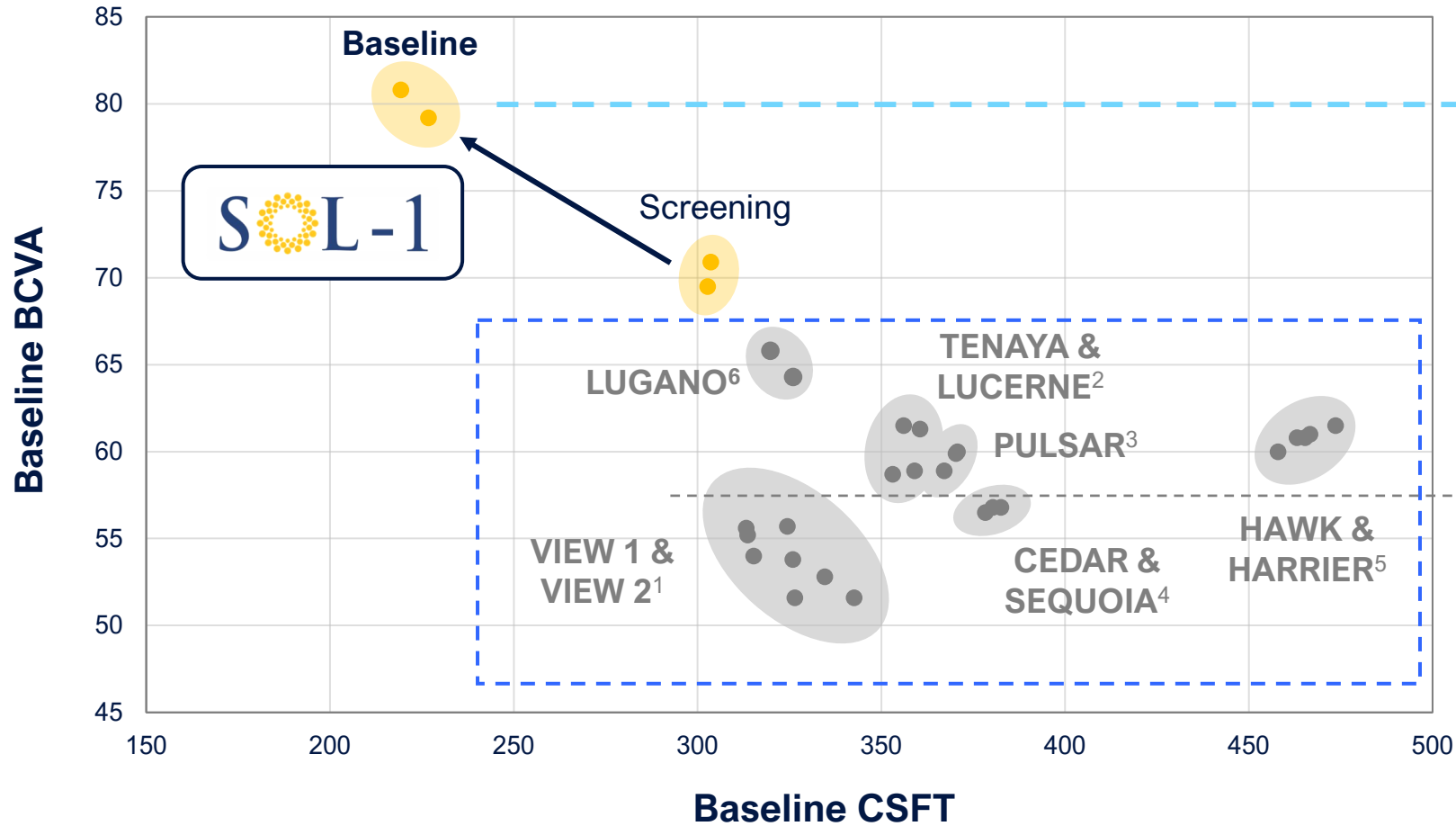
Baseline BCVA Across nAMD Trials



SOL-1 Evaluated a Distinct nAMD Cohort with Excellent Baseline Vision



Baseline BCVA Across nAMD Trials



SOL-1
mean BCVA: **81 letters (~20/25)**
mean CSFT: **219 μM**

nAMD Trials
mean BCVA: **52 to 66 letters (~20/100 to 20/50)**

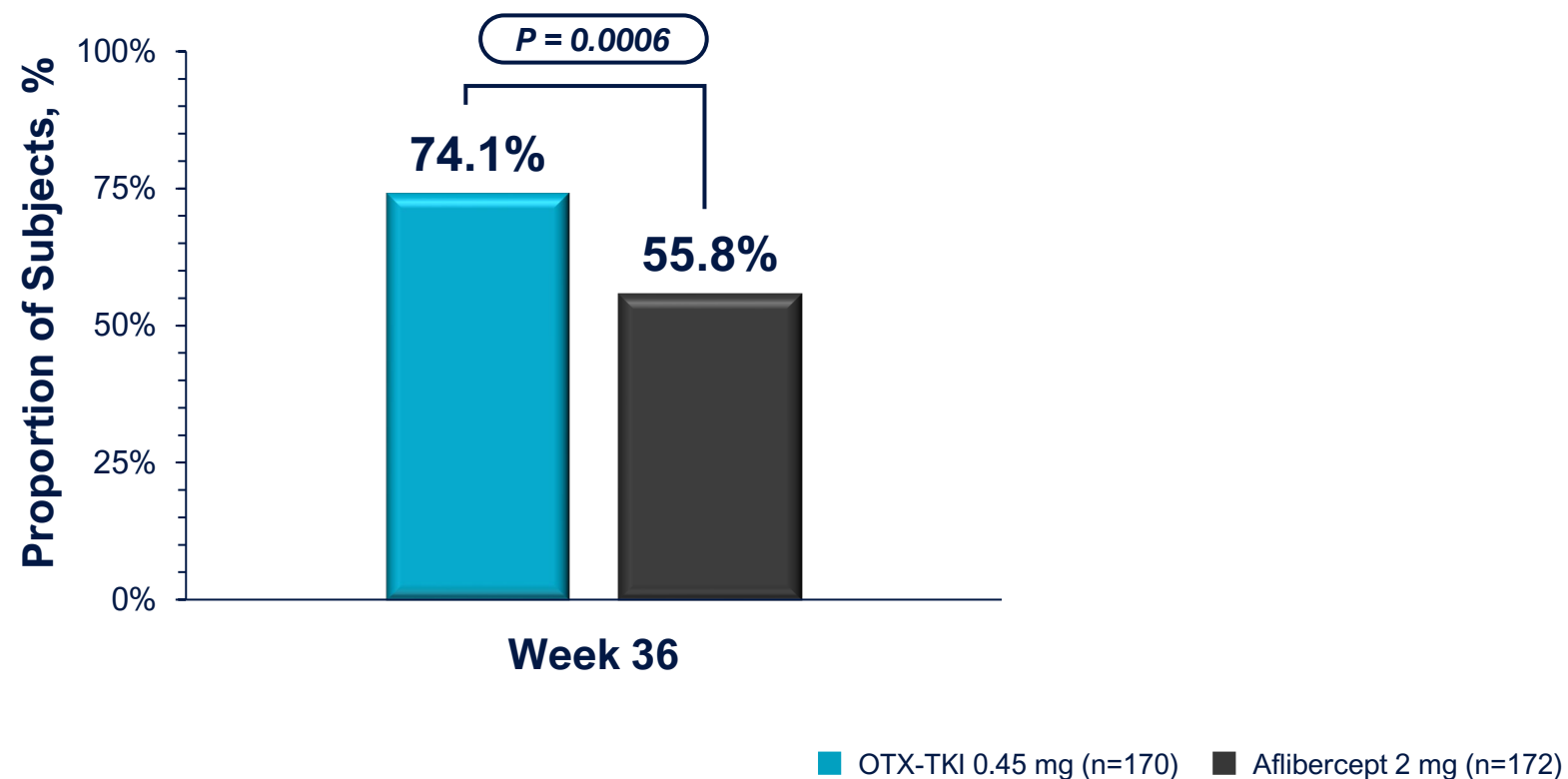
1. Heier JS, et al. *Ophthalmology*. 2012;119(12):2537-2548. 2. Heier JS, et al. *Lancet*. 2022;399(10326):729-740. 3. Lanzetta P, et al. *Lancet*. 2024;403(10432):1141-1152. 4. Kunimoto D, et al. *Ophthalmology*. 2020;127(10):1331-1344. 5. Dugel PU, et al. *Ophthalmology*. 2020;127(1):72-84. 6. Regillo CD. LUGANO Phase 3 trial of bioerodible EYP-1901 (vorolanib intravitreal insert) vs aflibercept in patients with neovascular age-related macular degeneration (nAMD): first-time vision and anatomic outcomes. Presented at: The Retina Society 59th Annual Scientific Meeting. Los Angeles, California. September 24, 2026. BCVA, best-corrected visual acuity; CSFT, central subfield thickness; nAMD, neovascular age-related macular degeneration

SOL-1: Results

Patricio G. Schlottmann, MD

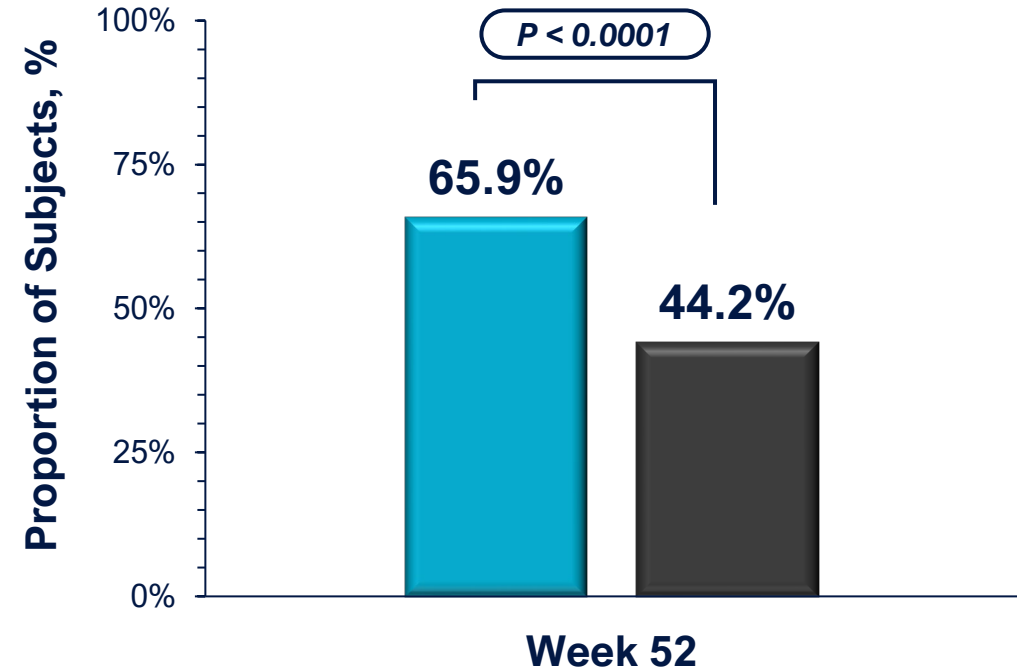
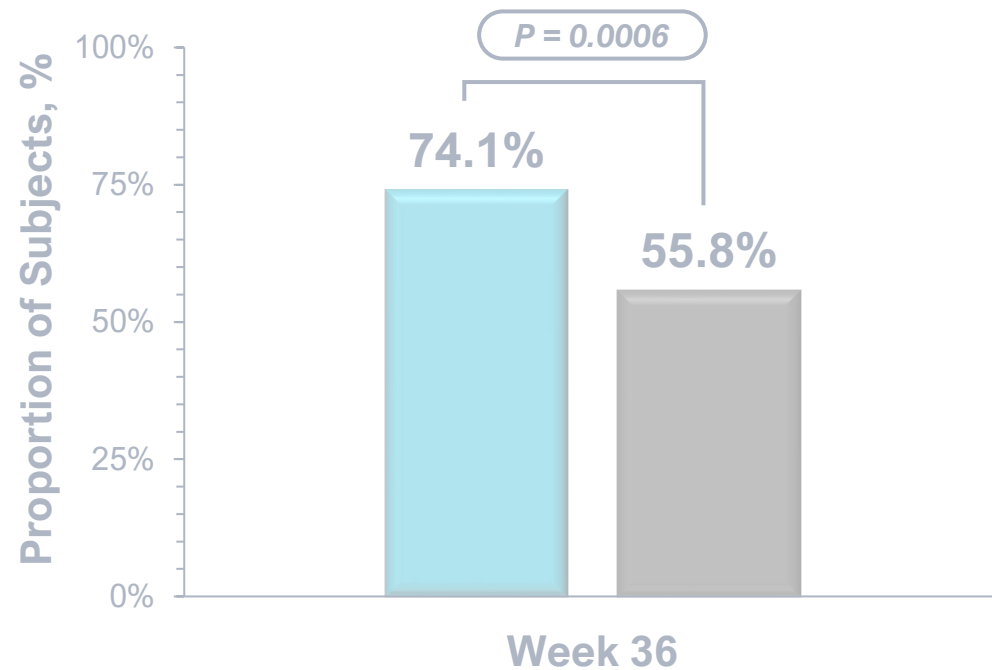
Primary Endpoint Successfully Met

Statistically Significant Higher Proportion of Subjects Maintained Visual Acuity* with OTX-TKI vs. Aflibercept 2 mg at Week 36



Difference in Proportion of Subjects Maintaining Visual Acuity Sustained Through Week 52

Key Secondary Endpoint: Maintenance of Visual Acuity* at Week 52

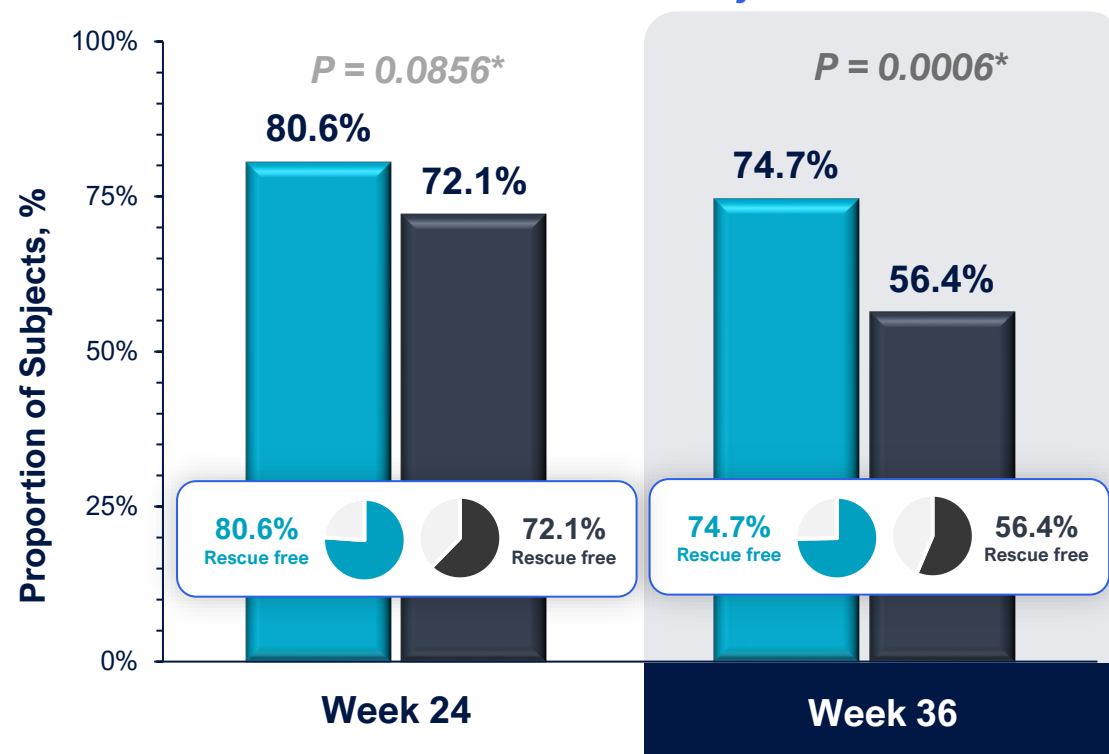


■ OTX-TKI 0.45 mg (n=170) ■ Aflibercept 2 mg (n=172)

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

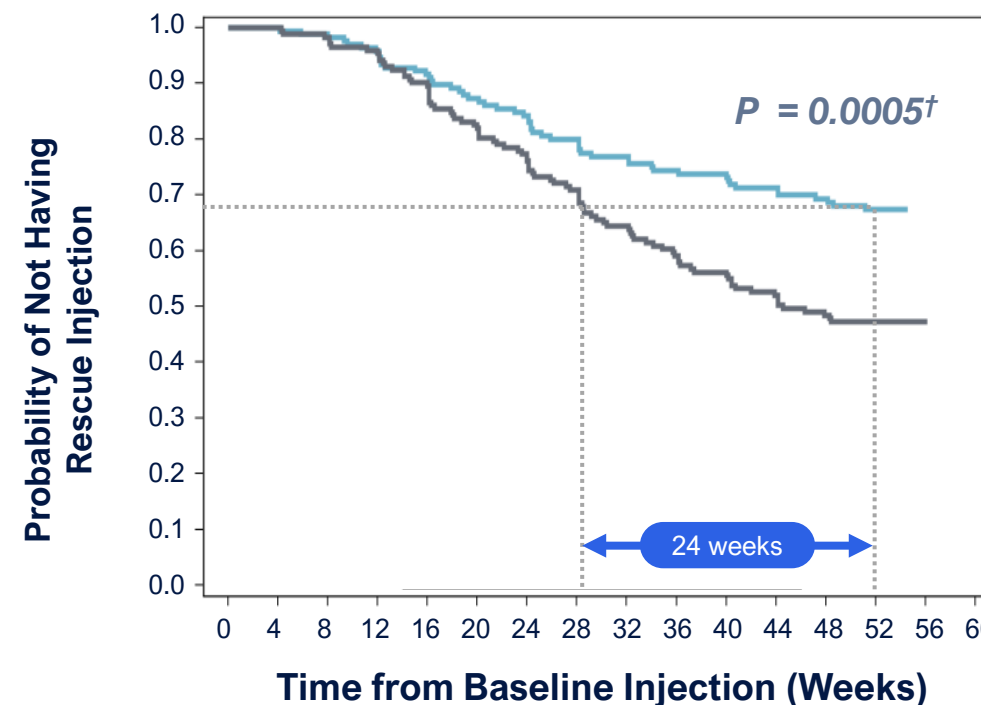
Proportion of Rescue-Free Subjects

Post Hoc Analysis



Time to First Rescue Treatment

Key Secondary Endpoint



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.



Retina
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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. Wyckoff 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>

On Average, OTX-TKI Subjects Maintained Vision and Anatomy, with Most Remaining Rescue-Free

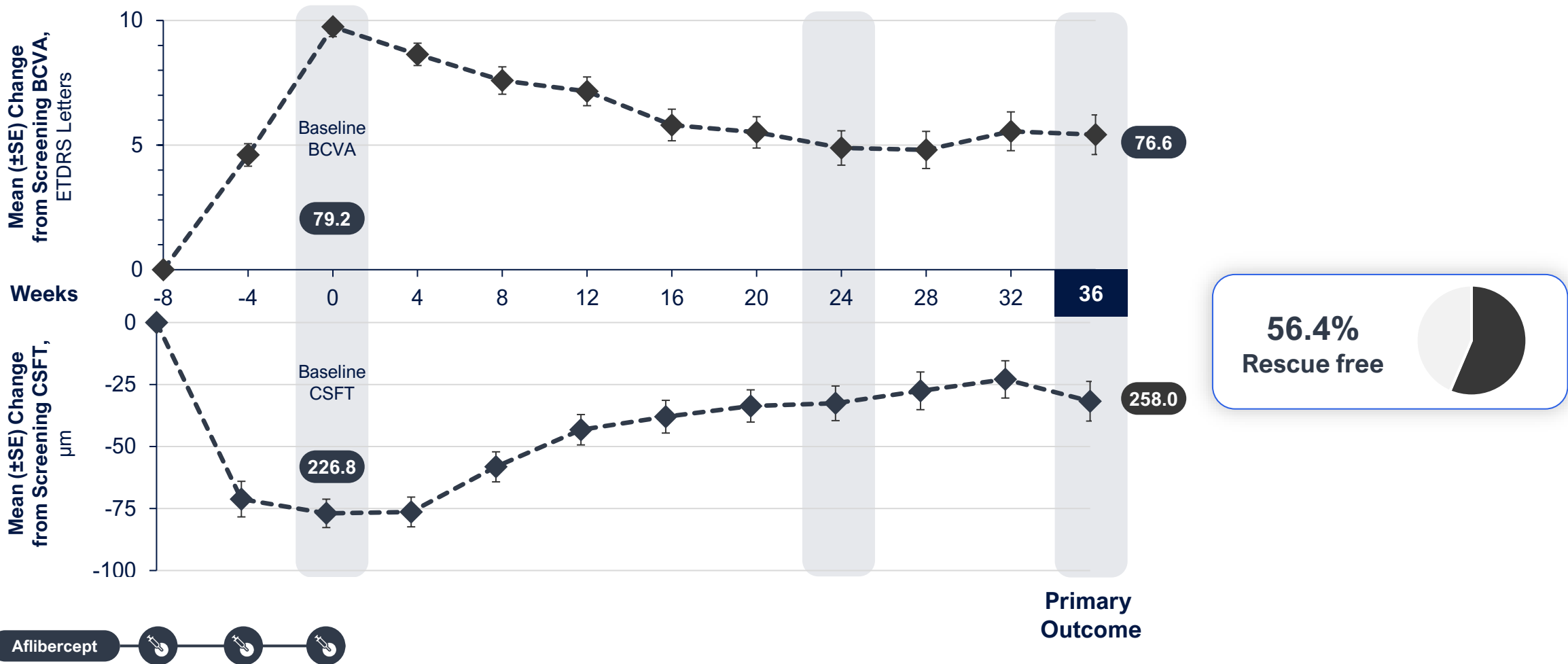
SOL-1

Post Hoc Analysis: Mean Change in BCVA and CSFT from Screening



On Average, OTX-TKI Subjects Maintained Vision and Anatomy, with Most Remaining Rescue-Free

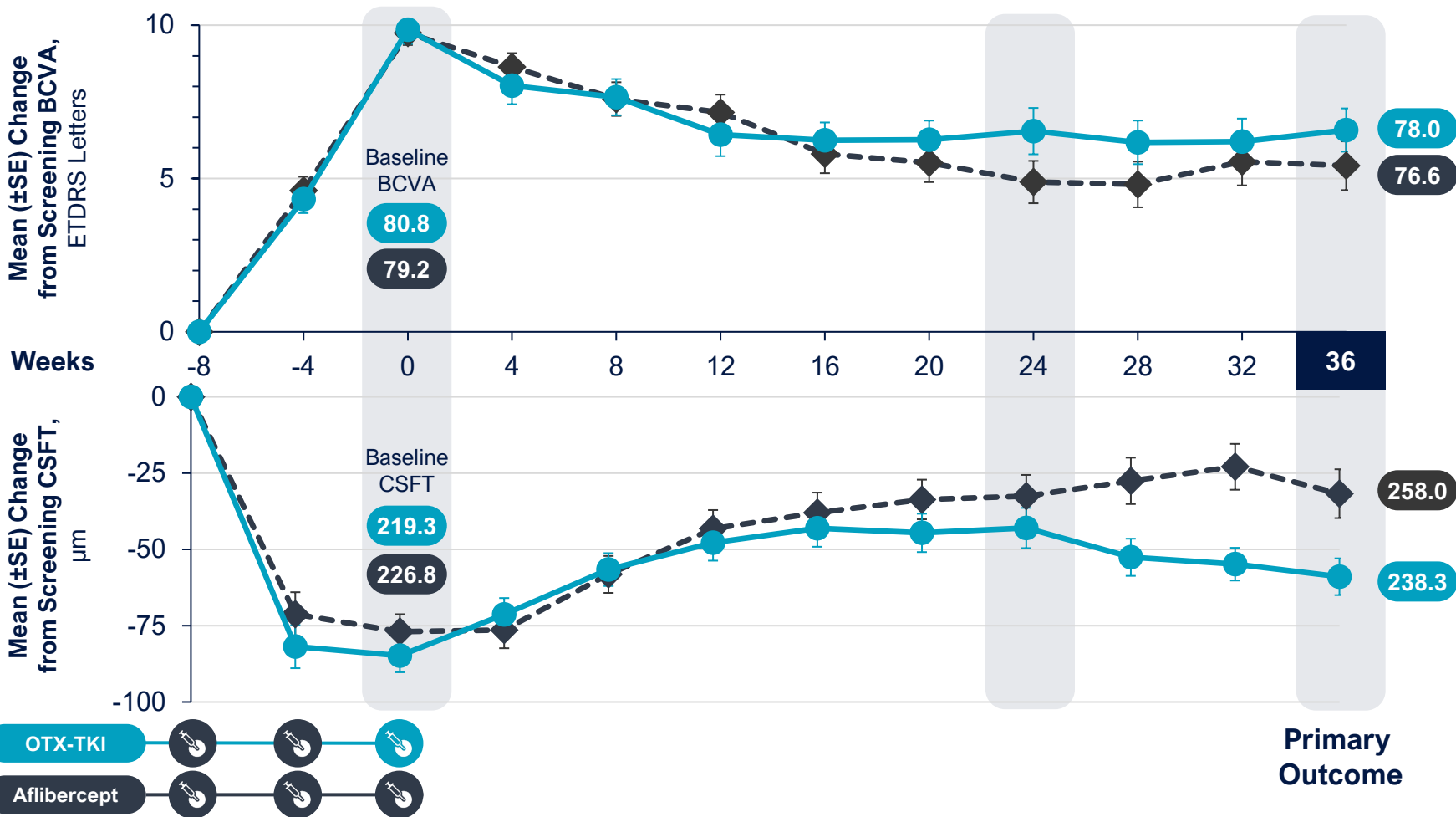
Post Hoc Analysis: Mean Change in BCVA and CSFT from Screening



On Average, OTX-TKI Subjects Maintained Vision and Anatomy, with Most Remaining Rescue-Free

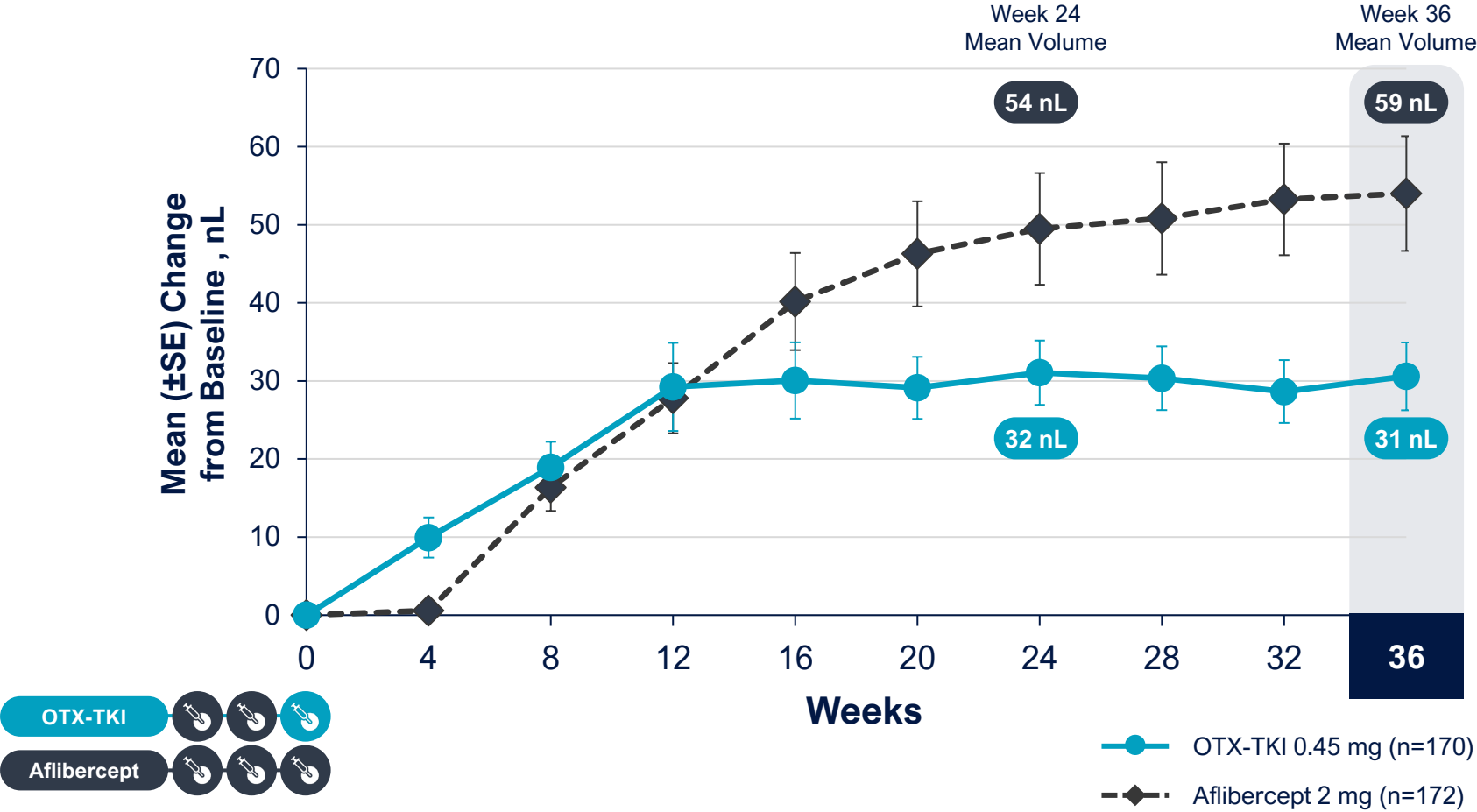


Post Hoc Analysis: Mean Change in BCVA and CSFT from Screening

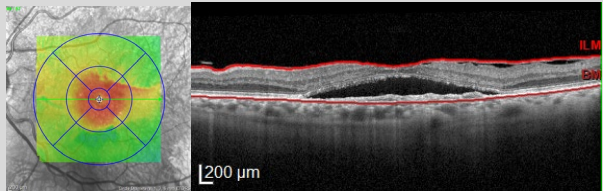


OTX-TKI Delivered Sustained Fluid Control

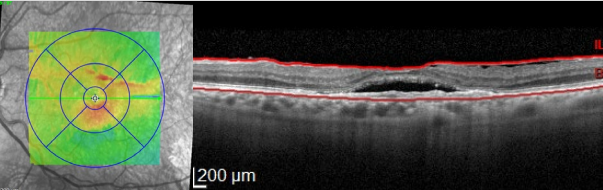
Prespecified Exploratory Analysis: Mean Change in Intra-Retinal and Sub-Retinal Fluid Volume



Total Fluid Volume: 60 nL



Total Fluid Volume: 30 nL



No Treatment or Procedure Related SAEs

Non-Ocular and Ocular Adverse Events in the Study Eye

Subjects with AEs Through Week 52, n (%)	OTX-TKI 0.45 mg n = 170	Aflibercept 2 mg n = 172
Non-ocular AEs		
≥ 1 AE	84 (49.4)	73 (42.4)
≥ 1 SAE	19 (11.2)	21 (12.2)
≥ 1 treatment-related AE	0	0
≥ 1 treatment-related SAE	0	0
≥ 1 study procedure-related AE	1 (0.6)	0
≥ 1 study procedure-related SAE	0	0
AE leading to study discontinuation	3 (1.8)	3 (1.7)
AE leading to death*	2 (1.2)	1 (0.6)
Ocular AEs in the study eye		
≥ 1 AE	90 (52.9)	58 (33.7)
≥ 1 SAE†	1 (0.6)	0
≥ 1 treatment-related AE	15 (8.8)	1 (0.6)
≥ 1 treatment-related SAE	0	0
≥ 1 study procedure-related AE	15 (8.8)	7 (4.1)
≥ 1 study procedure-related SAE	0	0
Ocular AE leading to study discontinuation	0	0

OTX-TKI was Generally Well Tolerated

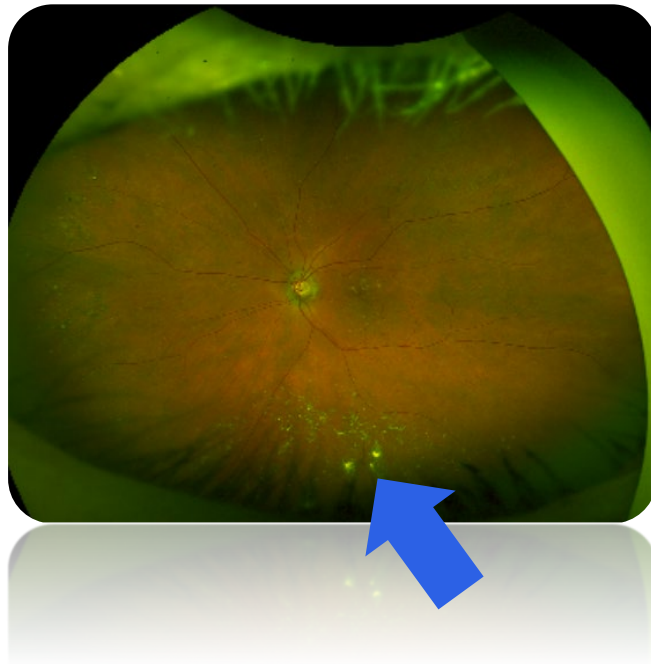
Ocular Adverse Events in the Study Eye

Subjects with Ocular AEs (> 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)

- Nine IOI 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**

Appearance of Floaters May Correspond to Hydrogel Dissolution and Drug Elution

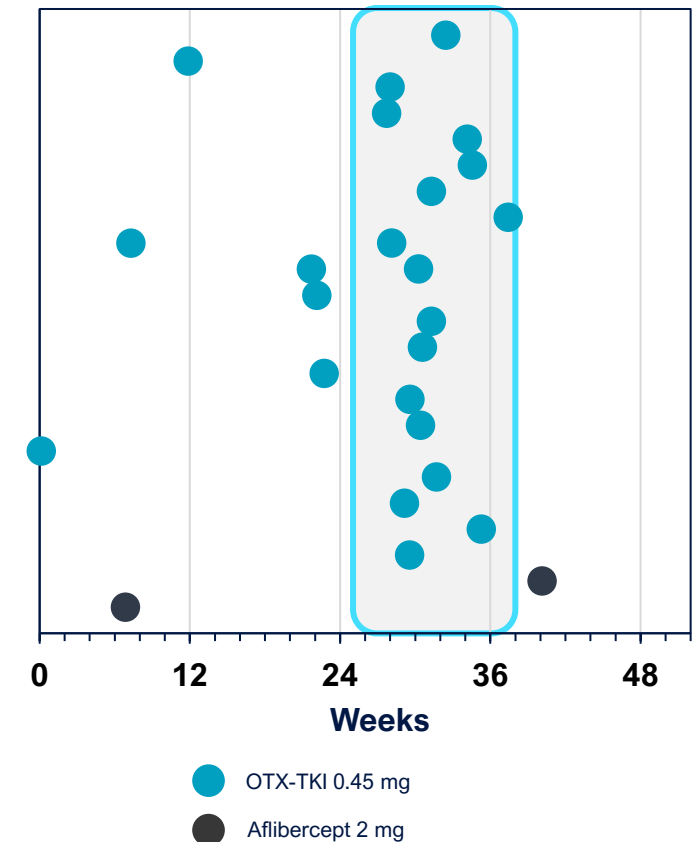
Evaluation of Vitreous Floaters



	OTX-TKI 0.45 mg n = 23*	Aflibercept 2 mg n = 2
Time to onset, days		
Mean (SD)	187.9 (64.0)	164.5 (164.8)
Median	207.0	164.5
BCVA change from prior visit before onset of floaters, ETDRS letters		
Mean change (SD)	-0.4 (5.0)	-5.5 (6.4)
Median change	0.0	-5.5

- All cases were mild to moderate in severity
- No evidence of IOI associated with floaters
- Onset of vitreous floaters AE 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**

Time to Onset

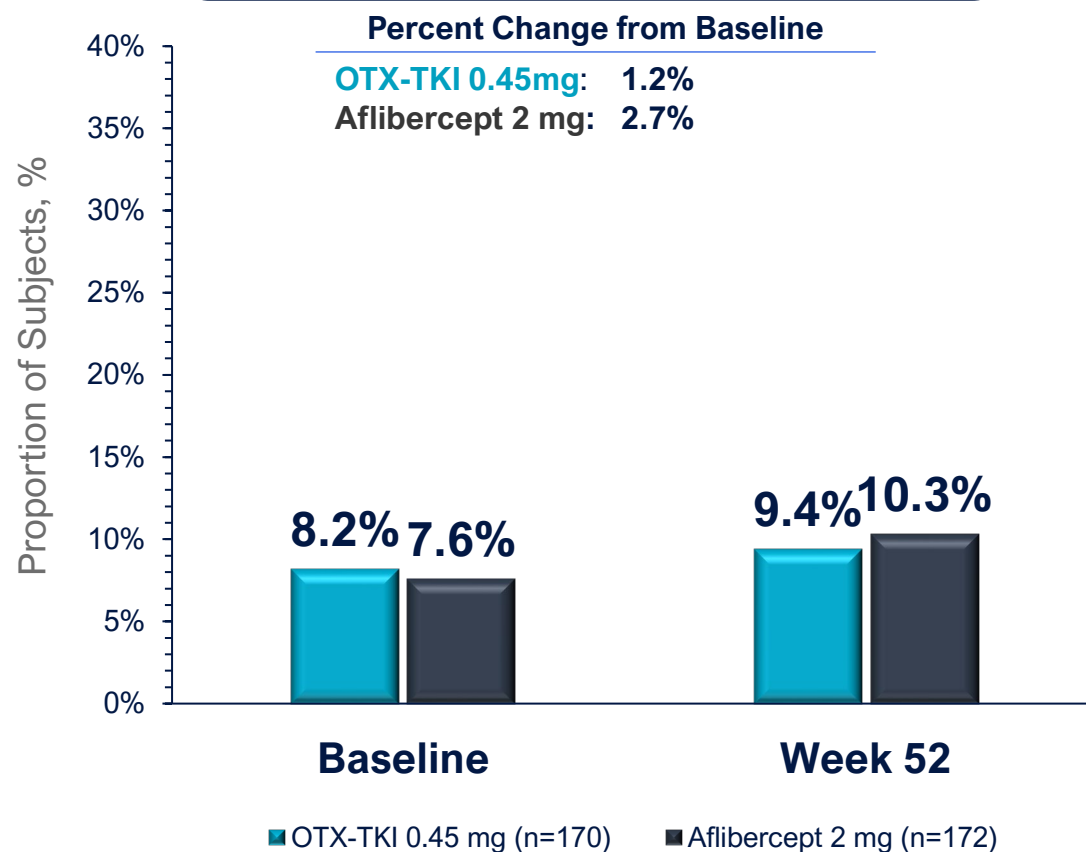


Incidence of Macular Atrophy in SOL-1

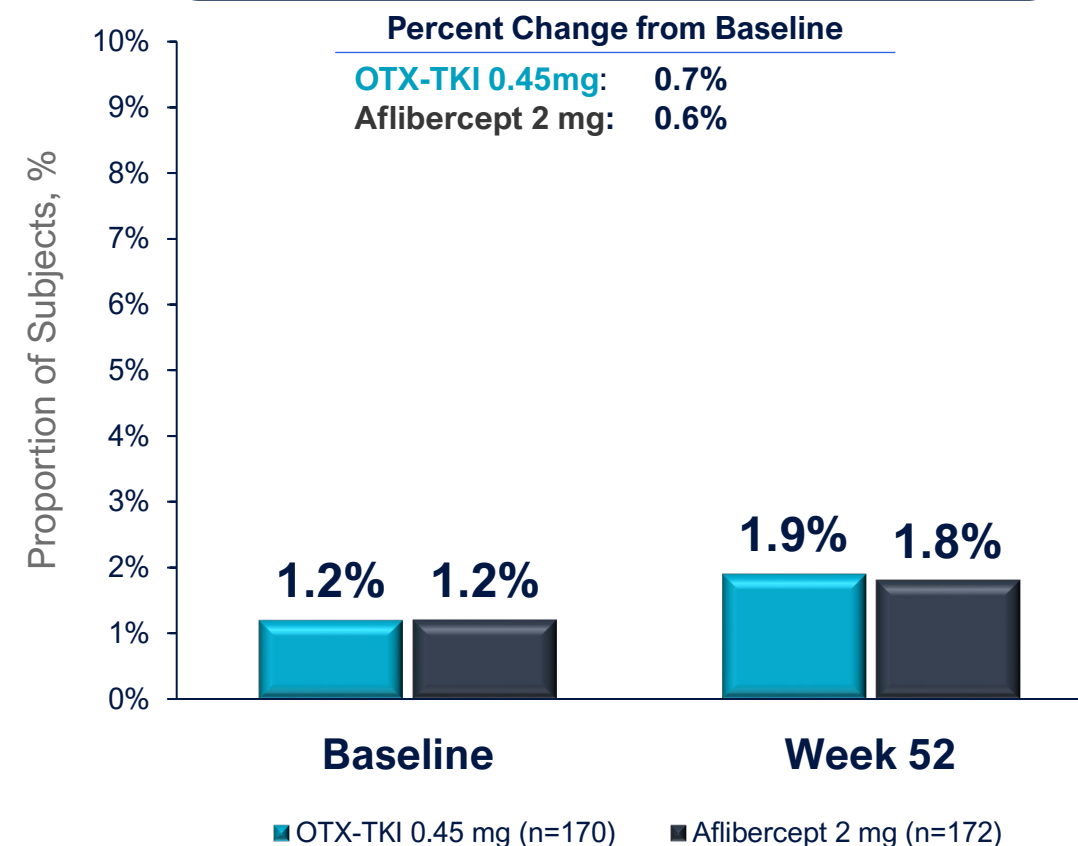
Safety Analysis

SOL-1

Any Macular Atrophy¹



Macular Atrophy in the Central 1mm¹



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

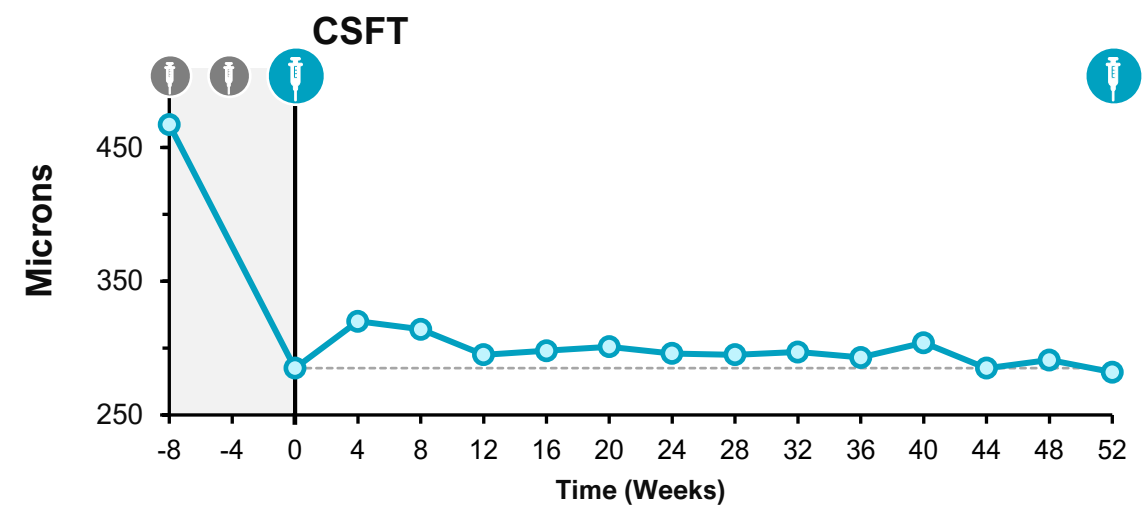
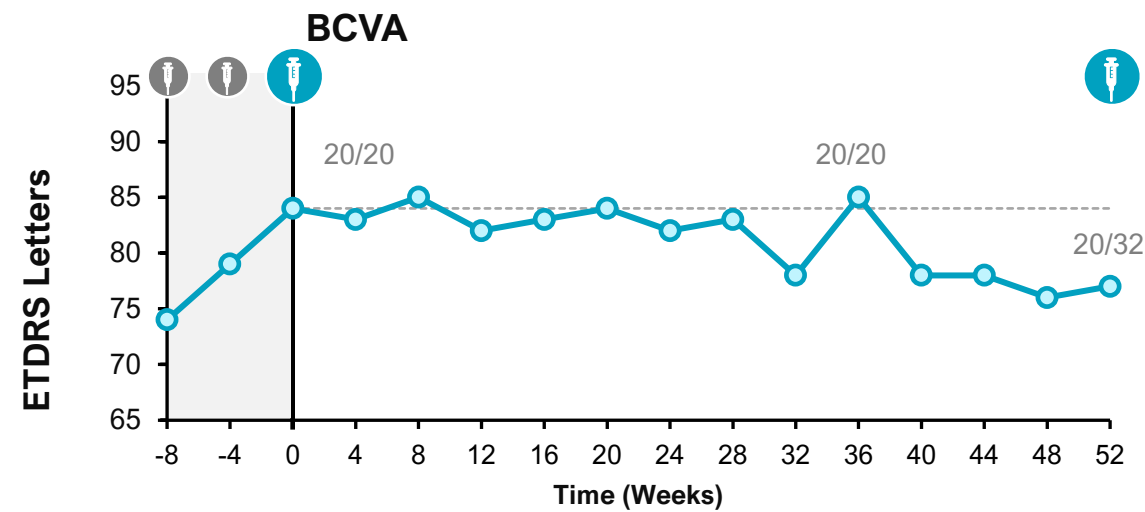
Well-Tolerated

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

Clinical Evidence

Dilsher S. Dhoot, MD, FASRS

OTX-TKI Case 1



Screening
Aflibercept (2mg)

OTX-TKI
(0.45mg)

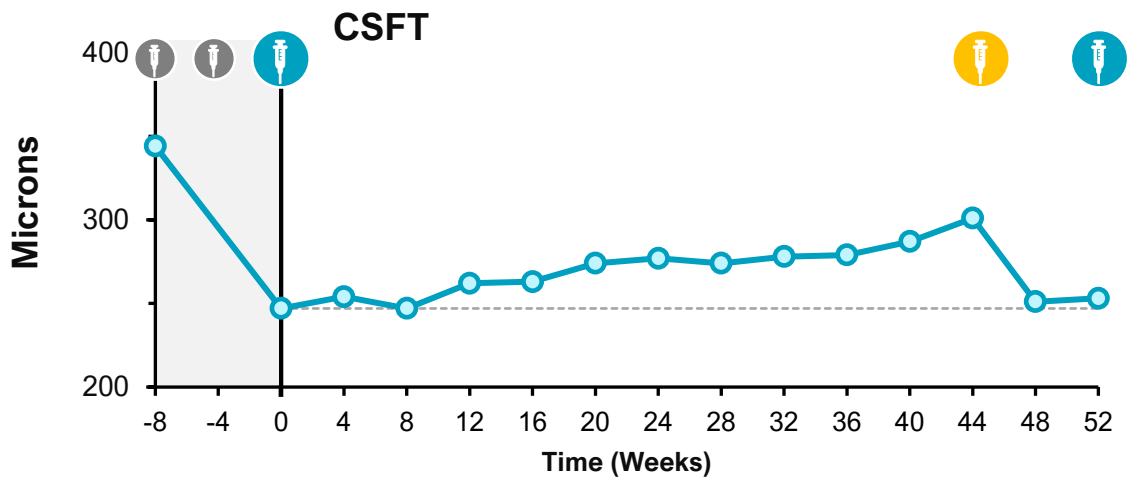
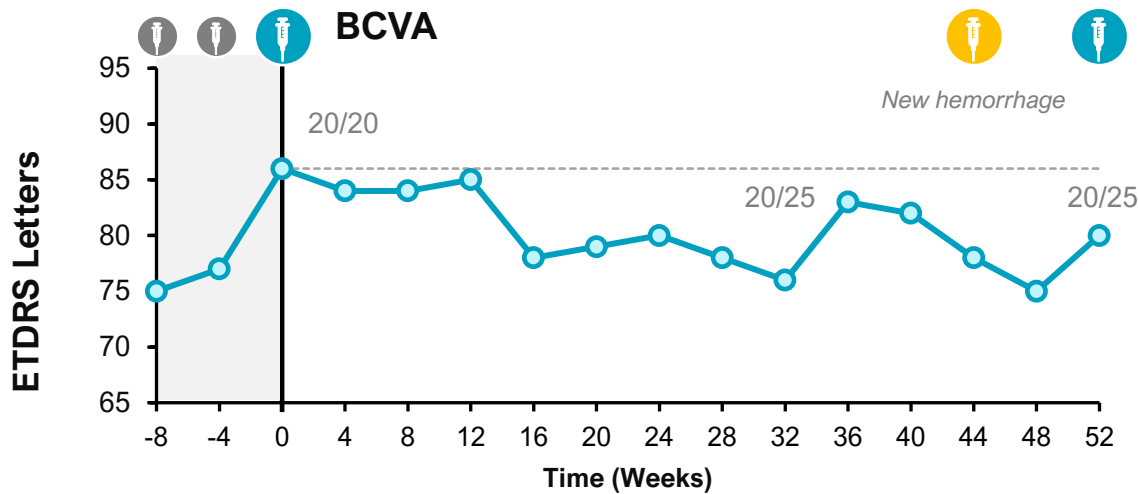
OCULAR
THERAPEUTIX

Retina
experience
redefined

Case study of one subject; individual results may vary
BCVA, best-corrected visual acuity; CSFT, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; Ltrs, letters

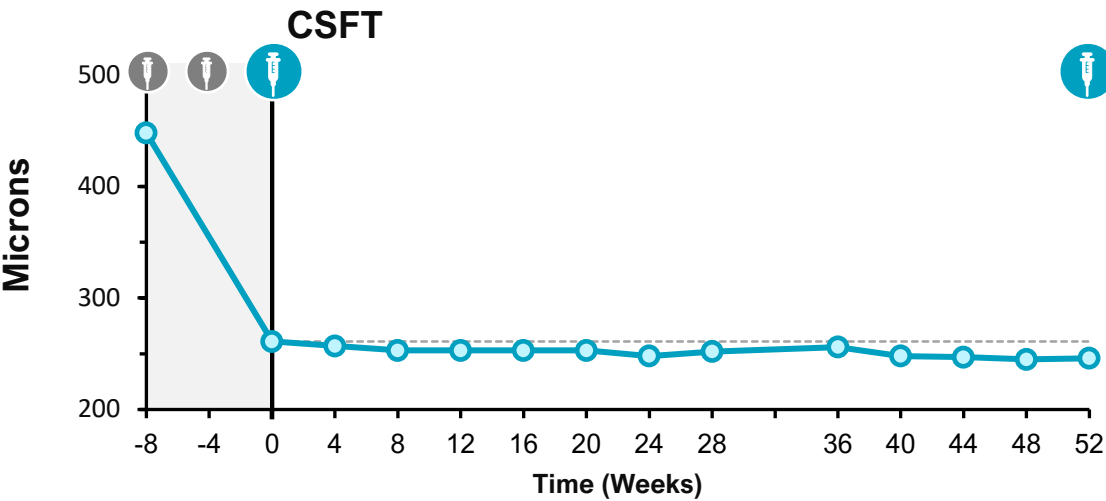
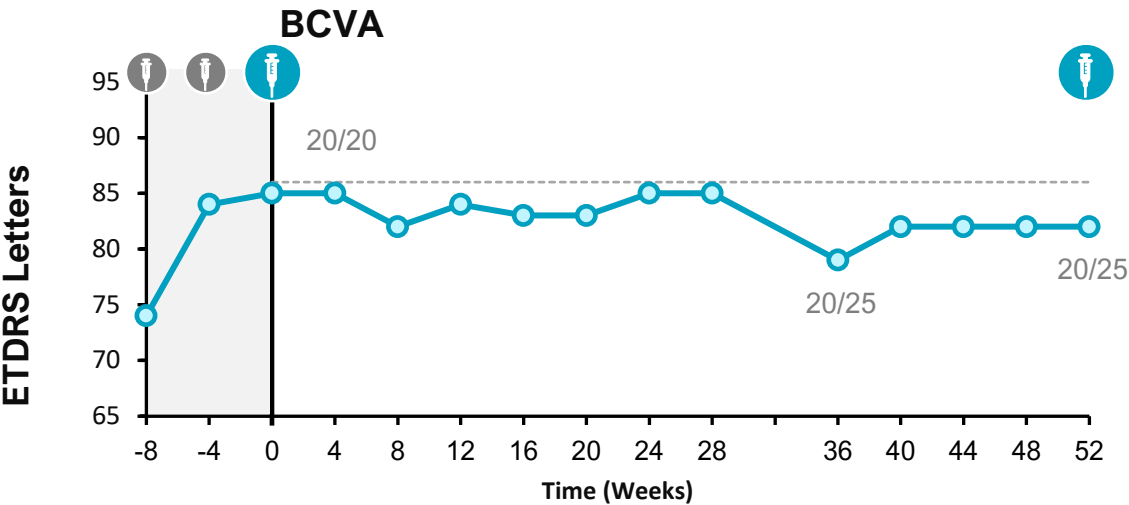
-8 Weeks	BCVA: 74 Ltrs (-10) CSFT: 467 μ m	
Baseline	BCVA: 84 Ltrs Snellen: 20/20 CSFT: 285 μ m	
Week 4	BCVA (Δ): 83 (-1) Ltrs CSFT (Δ): 320 (+35) μ m	
Week 12	BCVA (Δ): 82 (-2) Ltrs CSFT (Δ): 295 (+10) μ m	
Week 24	BCVA (Δ): 82 (-2) Ltrs CSFT (Δ): 296 (+11) μ m	
Week 36	BCVA (Δ): 85 (+1) Ltrs Snellen: 20/20 CSFT (Δ): 293 (+8) μ m	
Week 44	BCVA (Δ): 78 (-6) Ltrs CSFT (Δ): 285 (0) μ m	
Week 52	BCVA (Δ): 77 (-7) Ltrs Snellen: 20/32 CSFT (Δ): 282 (-3) μ m	

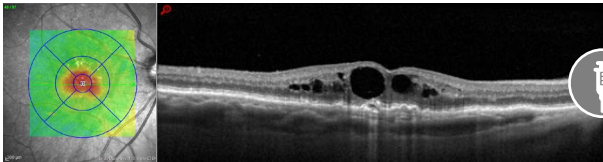
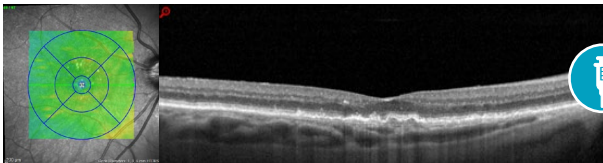
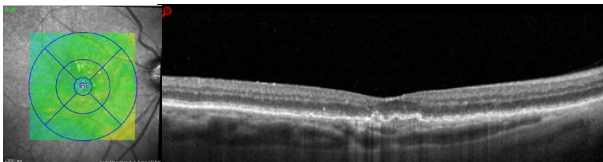
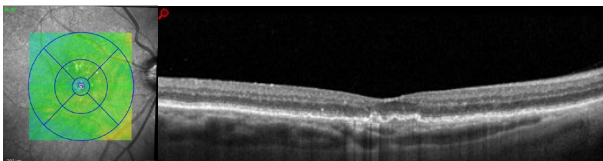
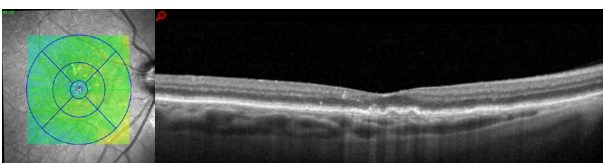
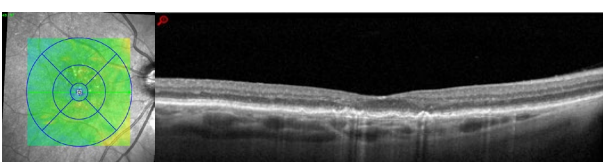
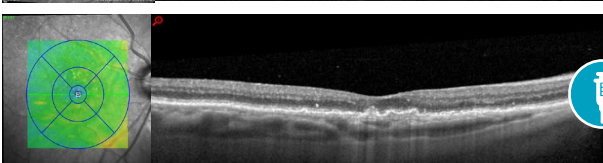
OTX-TKI Case 2



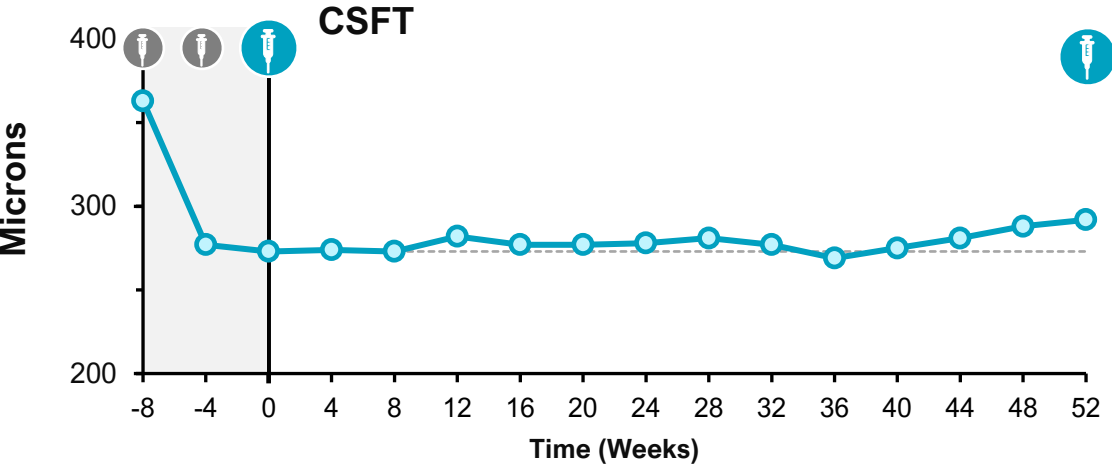
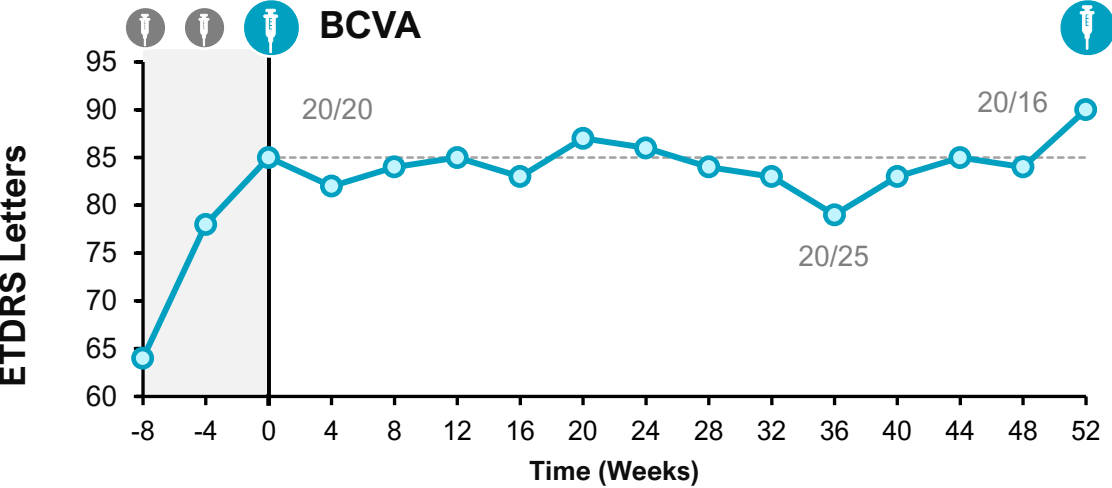
-8 Weeks	BCVA: 75 Ltrs CSFT: 344 µm	
Baseline	BCVA: 86 Ltrs Snellen: 20/20 CSFT: 247 µm	
Week 4	BCVA (Δ): 84 (-2) Ltrs CSFT (Δ): 254 (+7) µm	
Week 12	BCVA (Δ): 85 (-1) Ltrs CSFT (Δ): 262 (+15) µm	
Week 24	BCVA (Δ): 80 (-6) Ltrs CSFT (Δ): 277 (+30) µm	
Week 36	BCVA (Δ): 83 (-3) Ltrs Snellen: 20/25 CSFT (Δ): 279 (+32) µm	
Week 44	BCVA (Δ): 78 (-8) Ltrs CSFT (Δ): 301 (+54) µm	
Week 52	BCVA (Δ): 80 (-6) Ltrs Snellen: 20/25 CSFT (Δ): 253 (+6) µm	

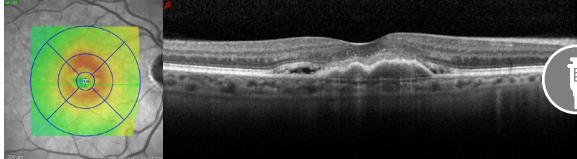
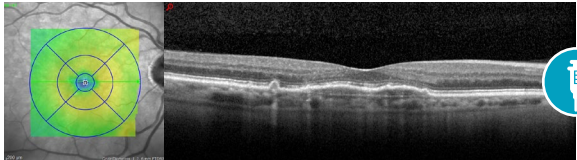
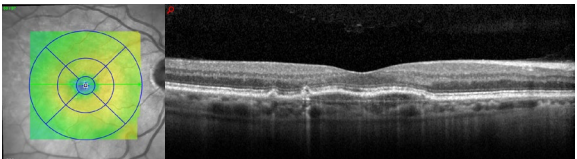
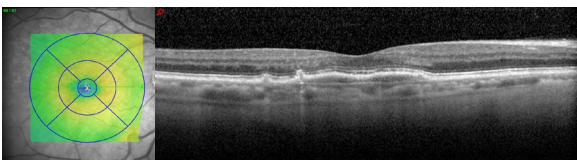
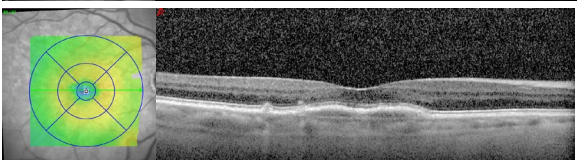
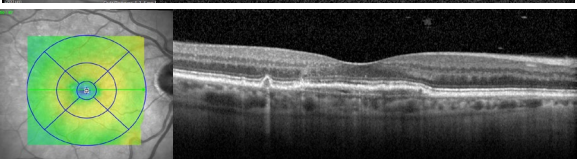
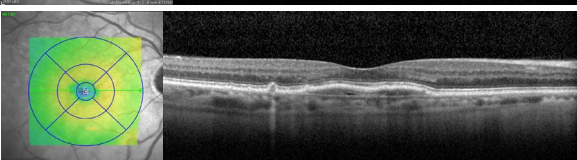
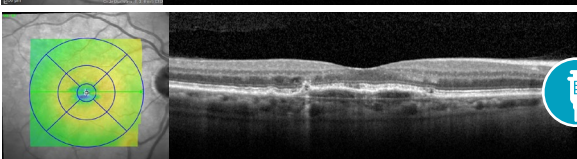
OTX-TKI Case 3



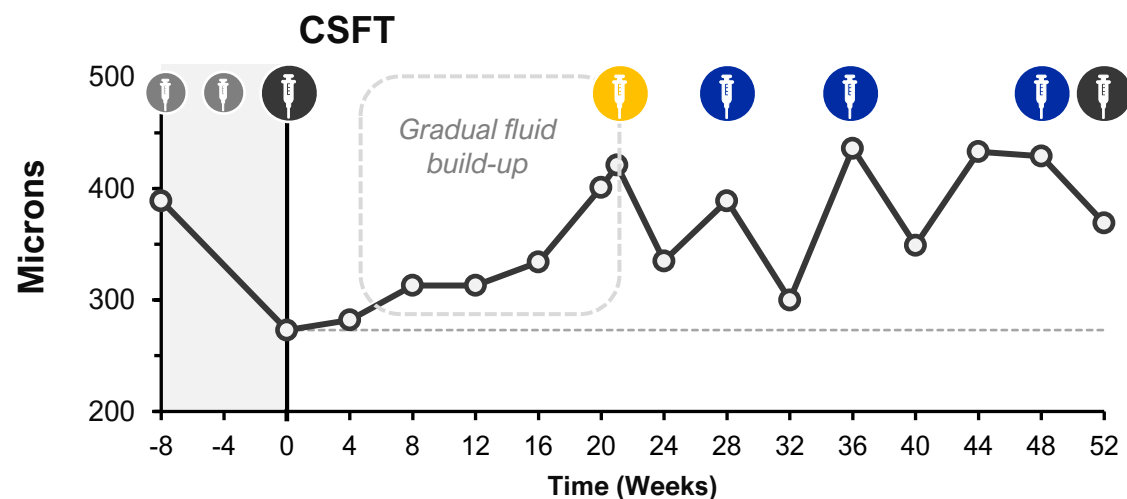
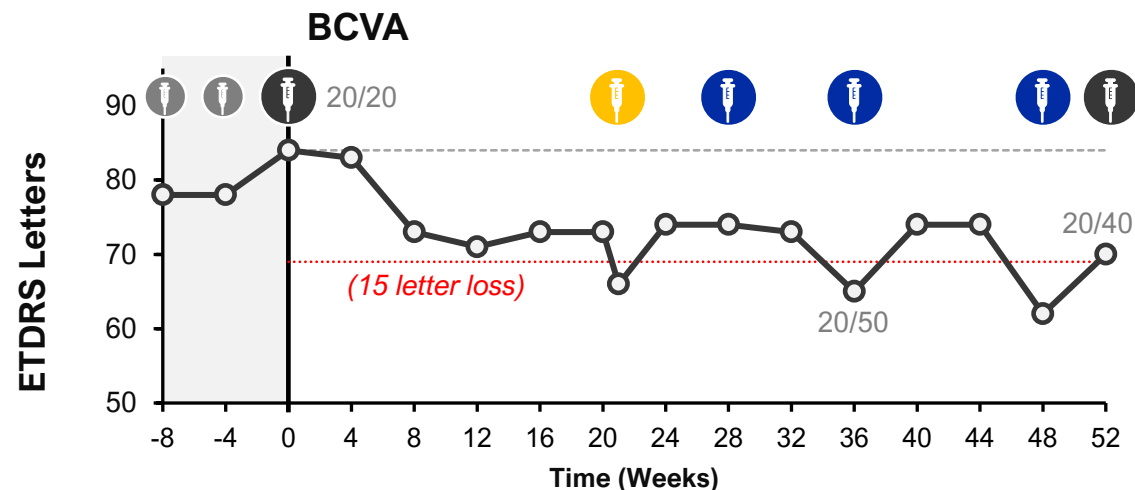
-8 Weeks	BCVA: 74 Ltrs CSFT: 448 µm	
Baseline	BCVA: 85 Ltrs Snellen: 20/20 CSFT: 261 µm	
Week 4	BCVA (Δ): 85 (0) Ltrs CSFT (Δ): 257 (-4) µm	
Week 12	BCVA (Δ): 84 (-1) Ltrs CSFT (Δ): 253 (-8) µm	
Week 24	BCVA (Δ): 85 (0) Ltrs CSFT (Δ): 248 (-13) µm	
Week 36	BCVA (Δ): 79 (-6) Ltrs Snellen: 20/25 CSFT (Δ): 256 (-5) µm	
Week 52	BCVA (Δ): 82 (-3) Ltrs Snellen: 20/25 CSFT (Δ): 246 (-15) µm	

OTX-TKI Case 4



-8 Weeks	BCVA: 64 Ltrs CSFT: 363 μ m	
Baseline	BCVA: 85 Ltrs Snellen: 20/20 CSFT: 273 μ m	
Week 4	BCVA (Δ): 82 (-3) Ltrs CSFT (Δ): 274 (+1) μ m	
Week 16	BCVA (Δ): 83 (-2) Ltrs CSFT (Δ): 277 (+4) μ m	
Week 24	BCVA (Δ): 86 (+1) Ltrs CSFT (Δ): 278 (+5) μ m	
Week 36	BCVA (Δ): 79 (-6) Ltrs Snellen: 20/26 CSFT (Δ): 269 (-4) μ m	
Week 44	BCVA (Δ): 85 (0) Ltrs CSFT (Δ): 281 (+8) μ m	
Week 52	BCVA (Δ): 90 (+5) Ltrs Snellen: 20/16 CSFT (Δ): 292 (+19) μ m	

Aflibercept Case 1



Screening Aflibercept (2mg)

Study Aflibercept (2 mg)

Per-Protocol Rescue Aflibercept (2mg)

Investigator Discretion Rescue

-8 Weeks	BCVA: 78 Ltrs CSFT: 389 μ m	
Baseline	BCVA: 84 Ltrs Snellen: 20/20 CSFT: 273 μ m	
Week 4	BCVA (Δ): 83 (-1) Ltrs CSFT (Δ): 282 (+9) μ m	
Week 8	BCVA (Δ): 73 (-11) Ltrs CSFT (Δ): 313 (+40) μ m	
Week 12	BCVA (Δ): 71 (-13) Ltrs CSFT (Δ): 313 (+40) μ m	
Week 16	BCVA (Δ): 73 (-11) Ltrs CSFT (Δ): 334 (+61) μ m	
Week 21 unscheduled	BCVA (Δ): 66 (-18) Ltrs CSFT (Δ): 421 (+148) μ m	

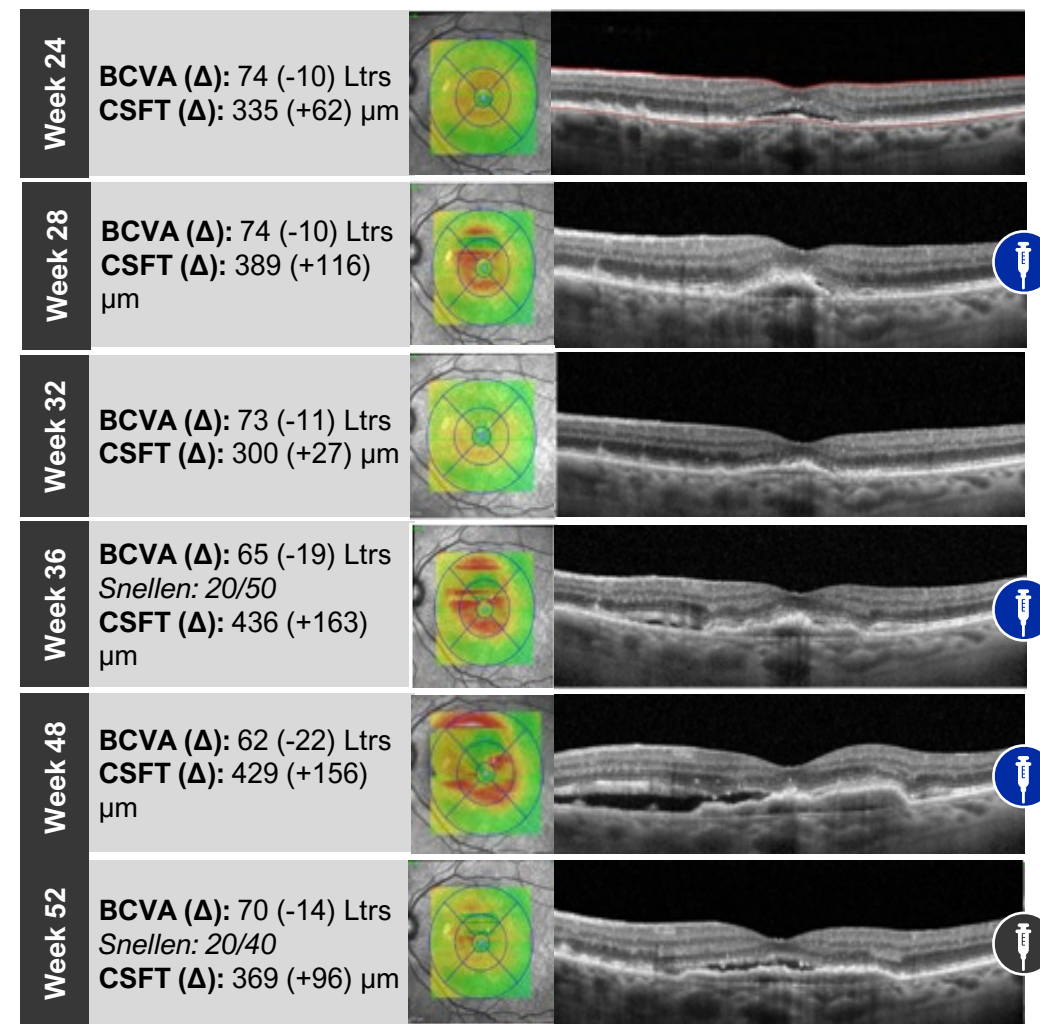
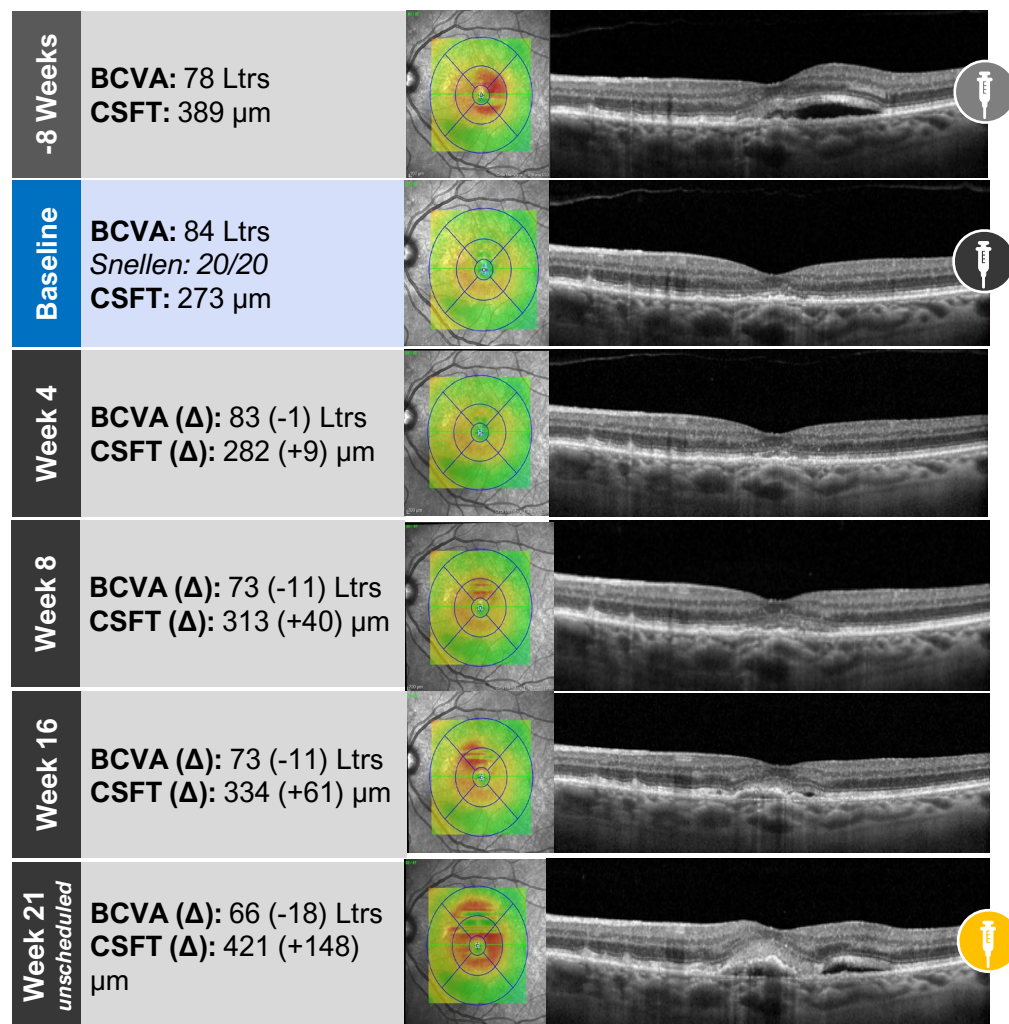
Aflibercept Case 1

 Screening
Aflibercept
(2mg)

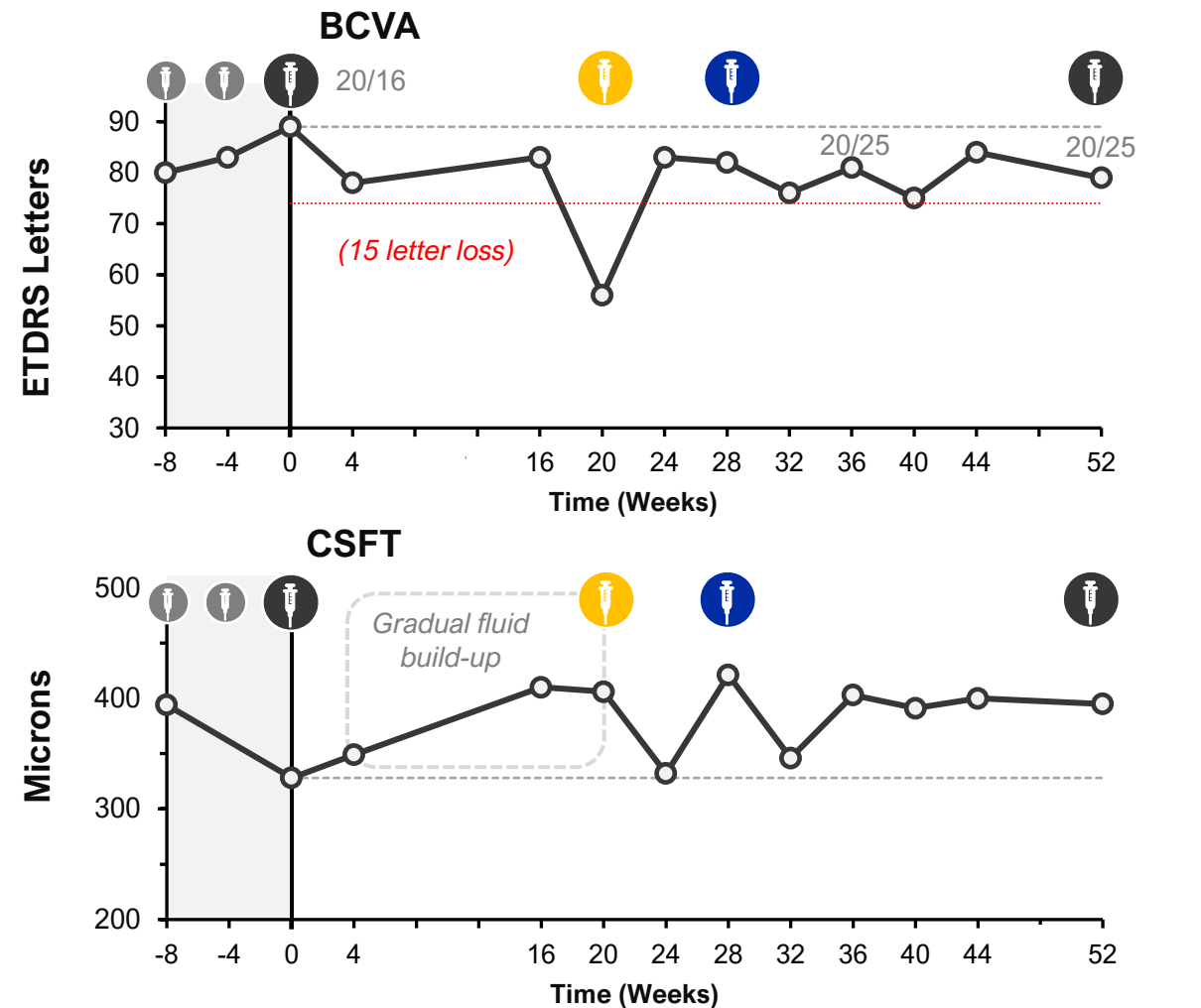
 Study
Aflibercept (2 mg)

 Per-Protocol Rescue
Aflibercept (2mg)

 Investigator
Discretion Rescue



Aflibercept Case 2



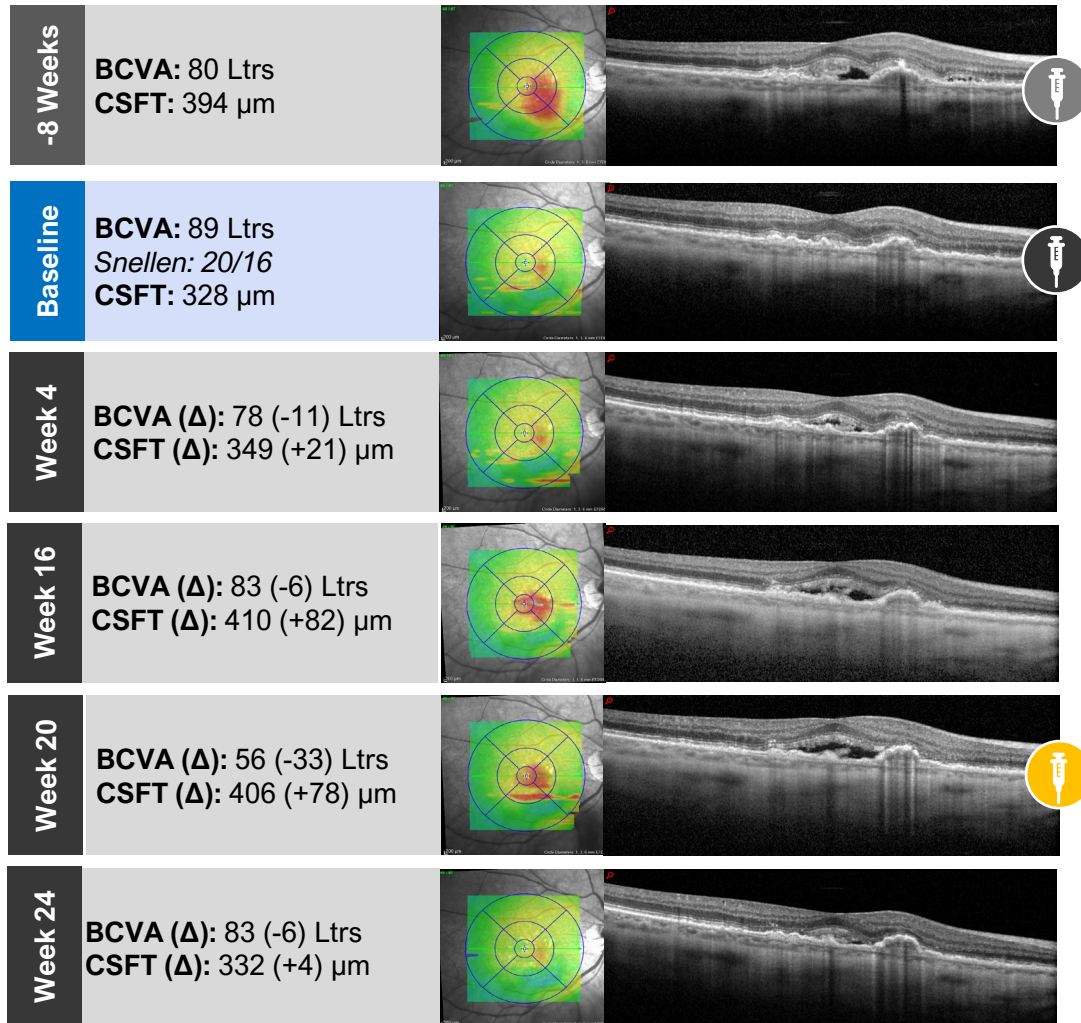
- Screening Aflibercept (2mg)
- Study Aflibercept (2 mg)
- Per-Protocol Rescue Aflibercept (2mg)
- Investigator Discretion Rescue



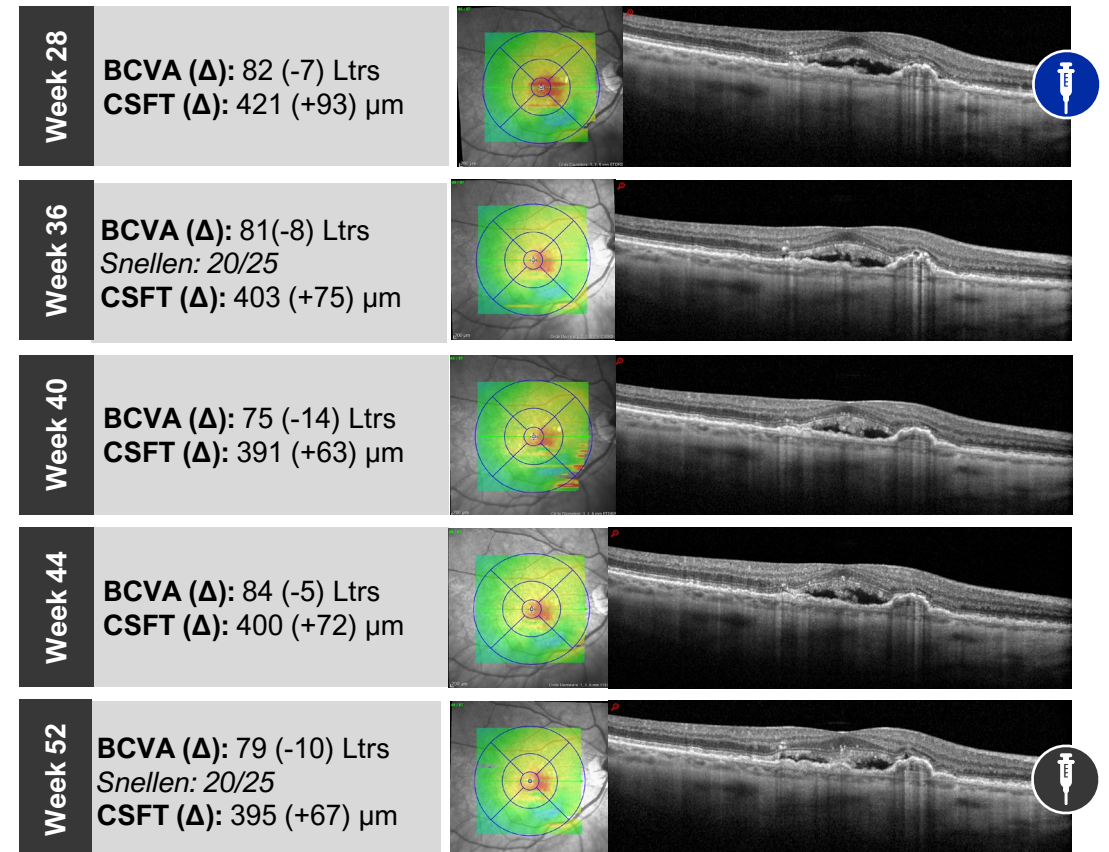
Subject missed W8/W12/W48 Visits
Case study of one subject; individual results may vary
BCVA, best-corrected visual acuity; CSFT, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; Ltrs, letters

-8 Weeks	BCVA: 80 Ltrs CSFT: 394 μ m	
Baseline	BCVA: 89 Ltrs Snellen: 20/16 CSFT: 328 μ m	
Week 4	BCVA (Δ): 78 (-11) Ltrs CSFT (Δ): 349 (+21) μ m	
Week 16	BCVA (Δ): 83 (-6) Ltrs CSFT (Δ): 410 (+82) μ m	
Week 20	BCVA (Δ): 56 (-33) Ltrs CSFT (Δ): 406 (+78) μ m	
Week 24	BCVA (Δ): 83 (-6) Ltrs CSFT (Δ): 332 (+4) μ m	
Week 28	BCVA (Δ): 82 (-7) Ltrs CSFT (Δ): 421 (+93) μ m	
Week 36	BCVA (Δ): 81(-8) Ltrs Snellen: 20/25 CSFT (Δ): 403 (+75) μ m	

Aflibercept Case 2



Screening Aflibercept (2mg) injection
 Study Aflibercept (2 mg) administration
 Per-Protocol Rescue Aflibercept (2mg)
 Investigator Discretion Rescue



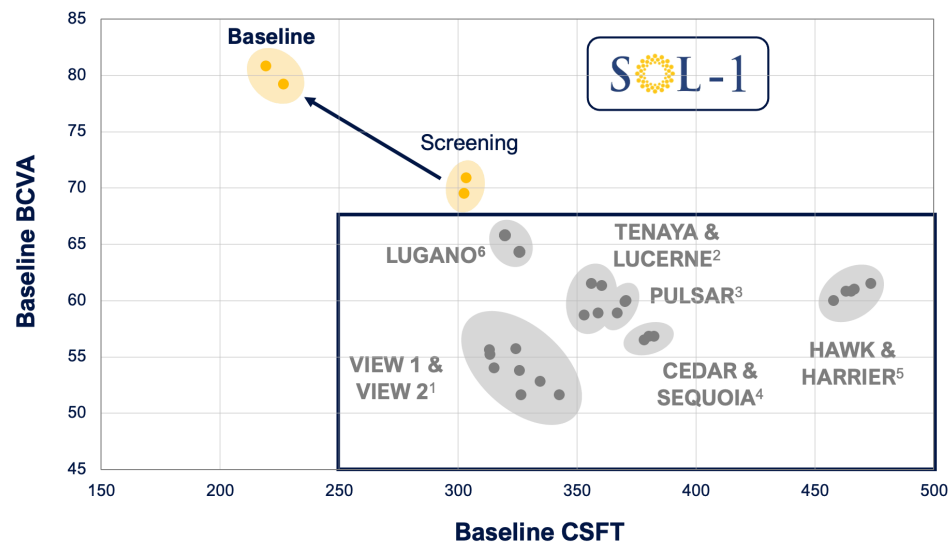
Key Insights

Adnan Tufail MBBS, MD, FRCOphth

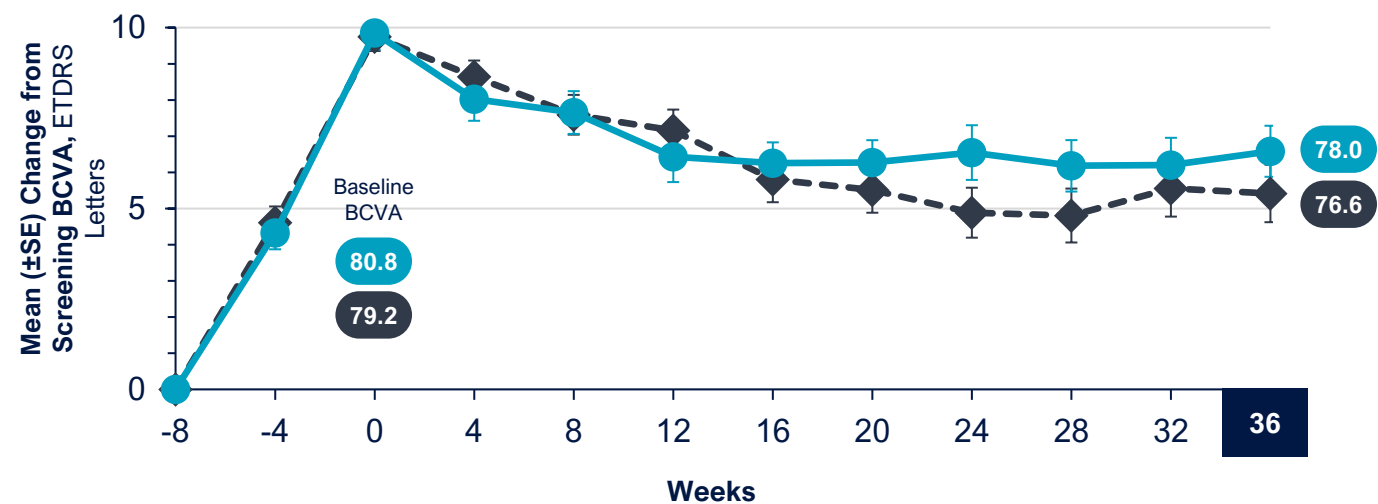
SOL-1 Evaluated a Distinct nAMD Cohort with Excellent Baseline Vision



Baseline BCVA Across nAMD Trials



SOL-1 : Mean Change in BCVA from Screening Post Hoc Analysis

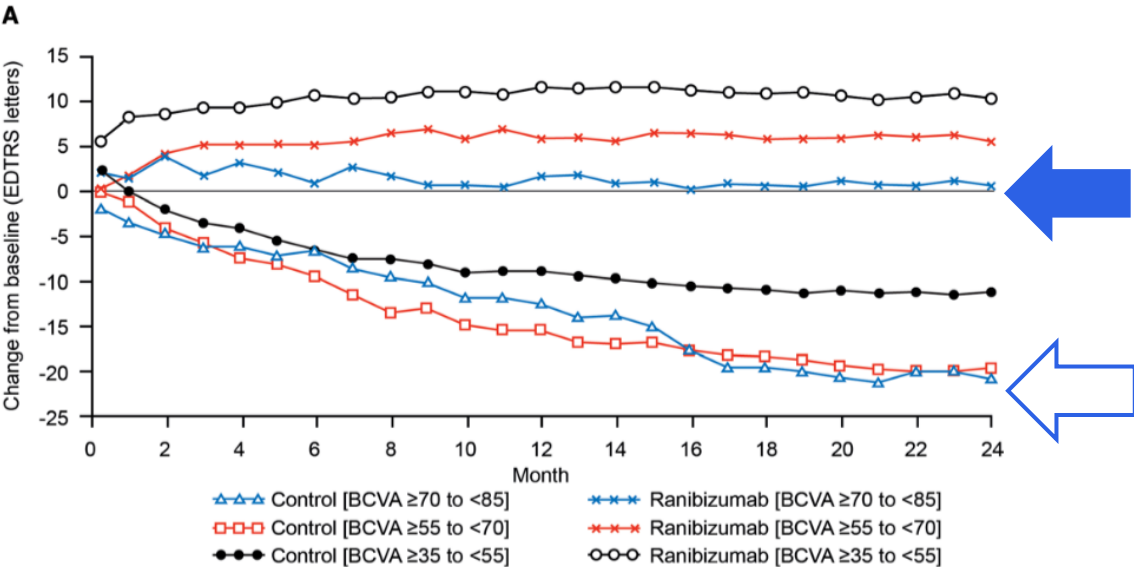


Does Reduced Potential for Visual Acuity Gain Occur in Pivotal Trials?

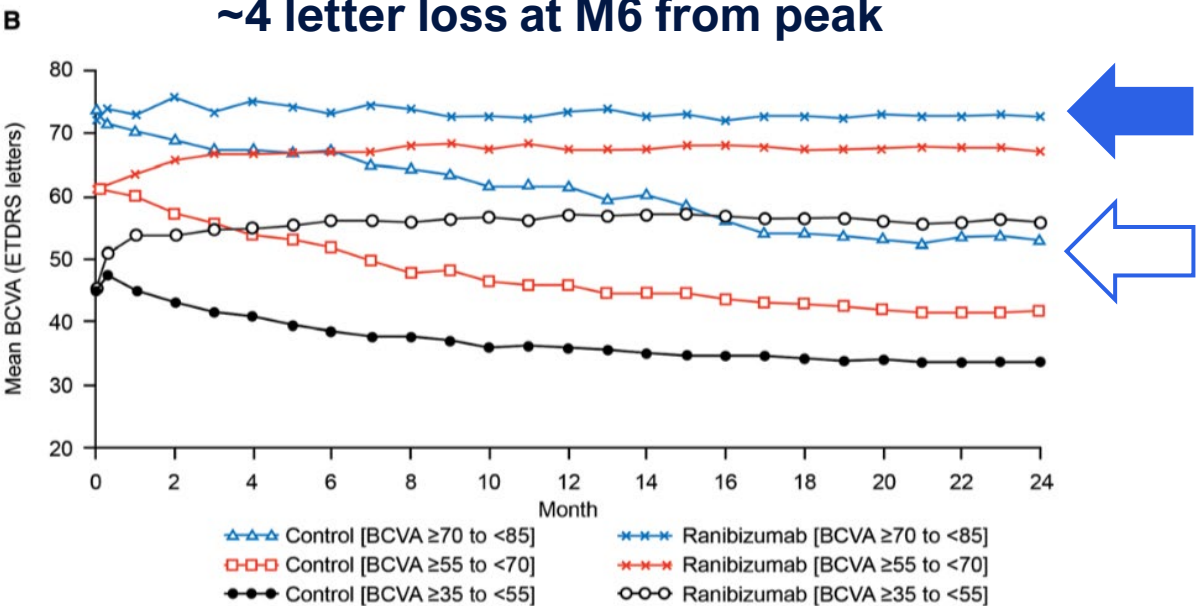
Sub-Analysis of ANCHOR and MARINA

Visual benefit versus visual gain: what is the effect of baseline covariants in the treatment arm relative to the control arm? A pooled analysis of ANCHOR and MARINA

Adnan Tufail ¹, Philippe Margaron, ² Tadhg Guerin, ³ Michael Larsen ⁴



In good VA group (baseline 70-85 letters),
~4 letter loss at M6 from peak

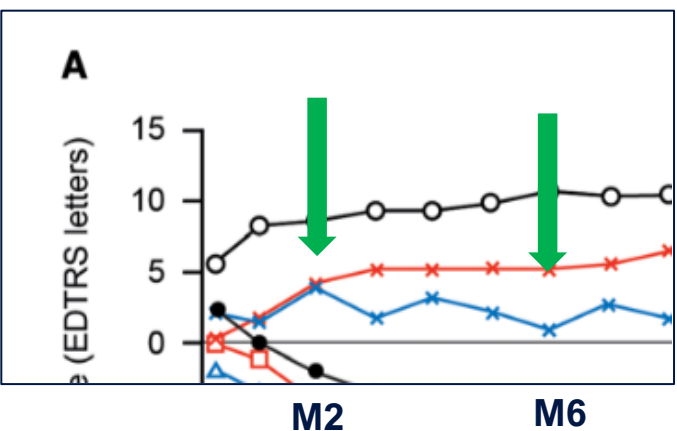
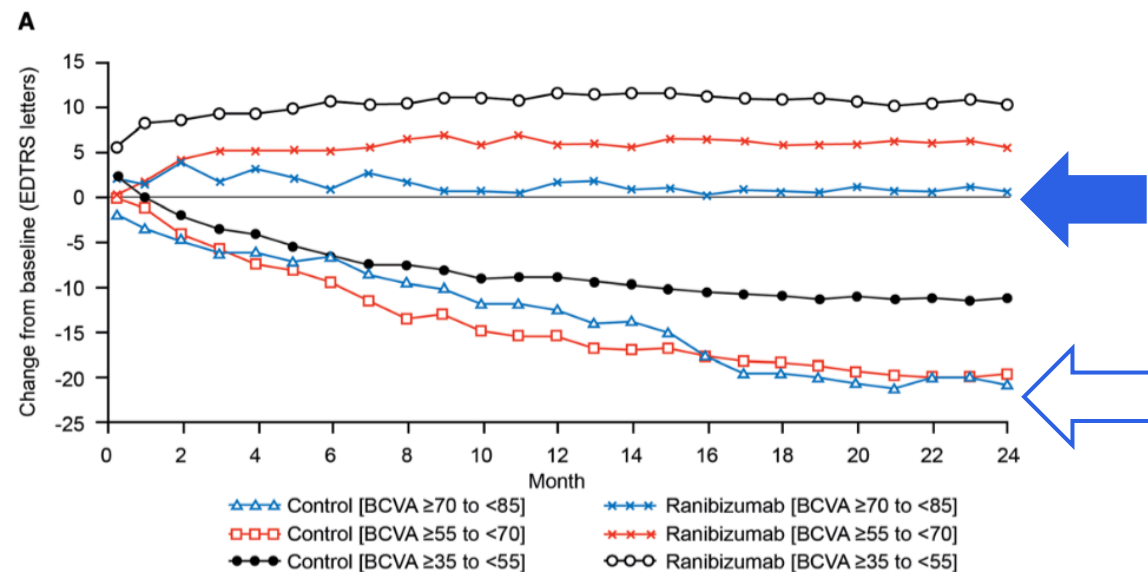


Does Reduced Potential for Visual Acuity Gain Occur in Pivotal Trials?

Sub-Analysis of ANCHOR and MARINA

Visual benefit versus visual gain: what is the effect of baseline covariants in the treatment arm relative to the control arm? A pooled analysis of ANCHOR and MARINA

Adnan Tufail ¹, Philippe Margaron, ² Tadhg Guerin, ³ Michael Larsen ⁴

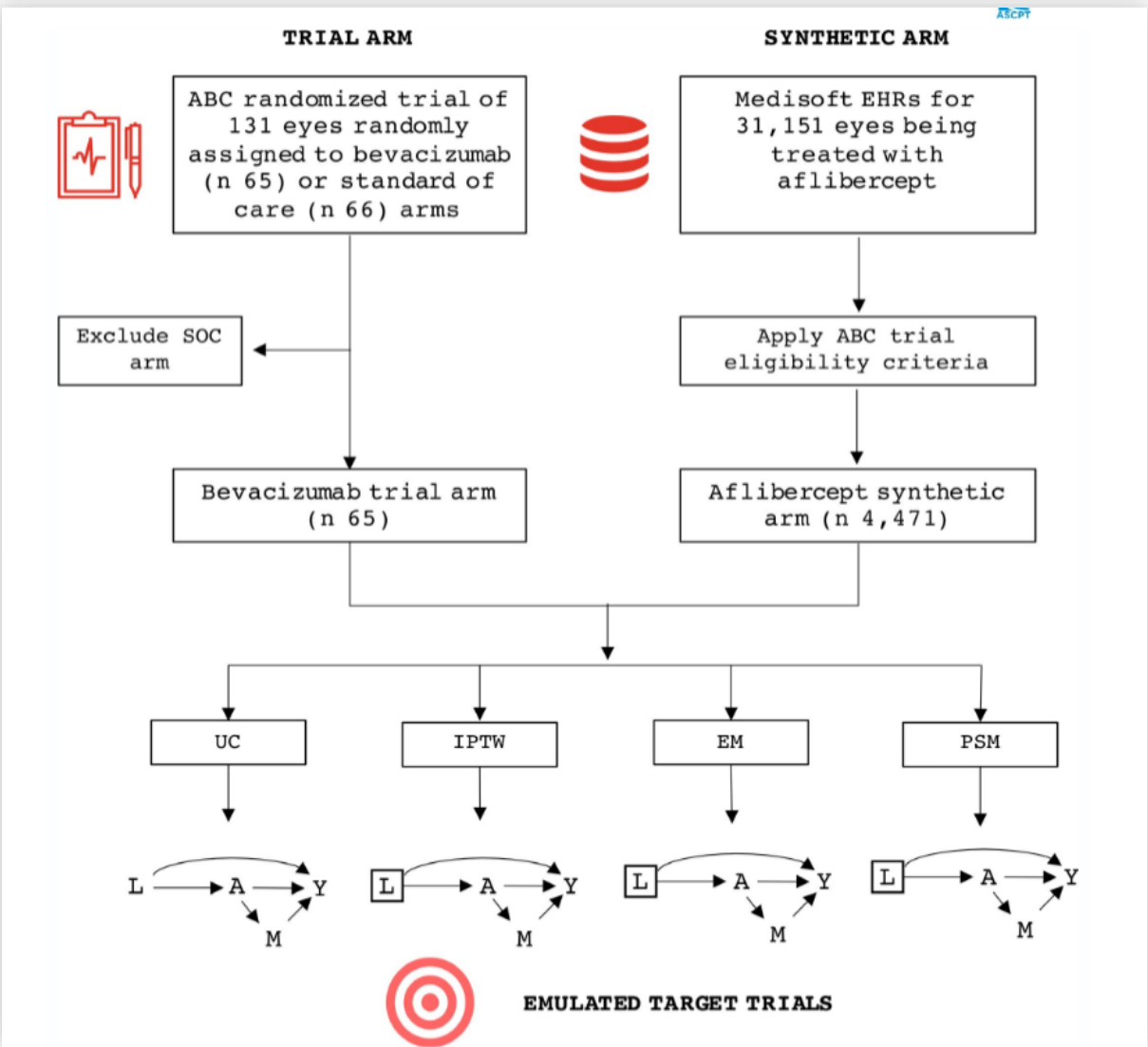


ARTICLE

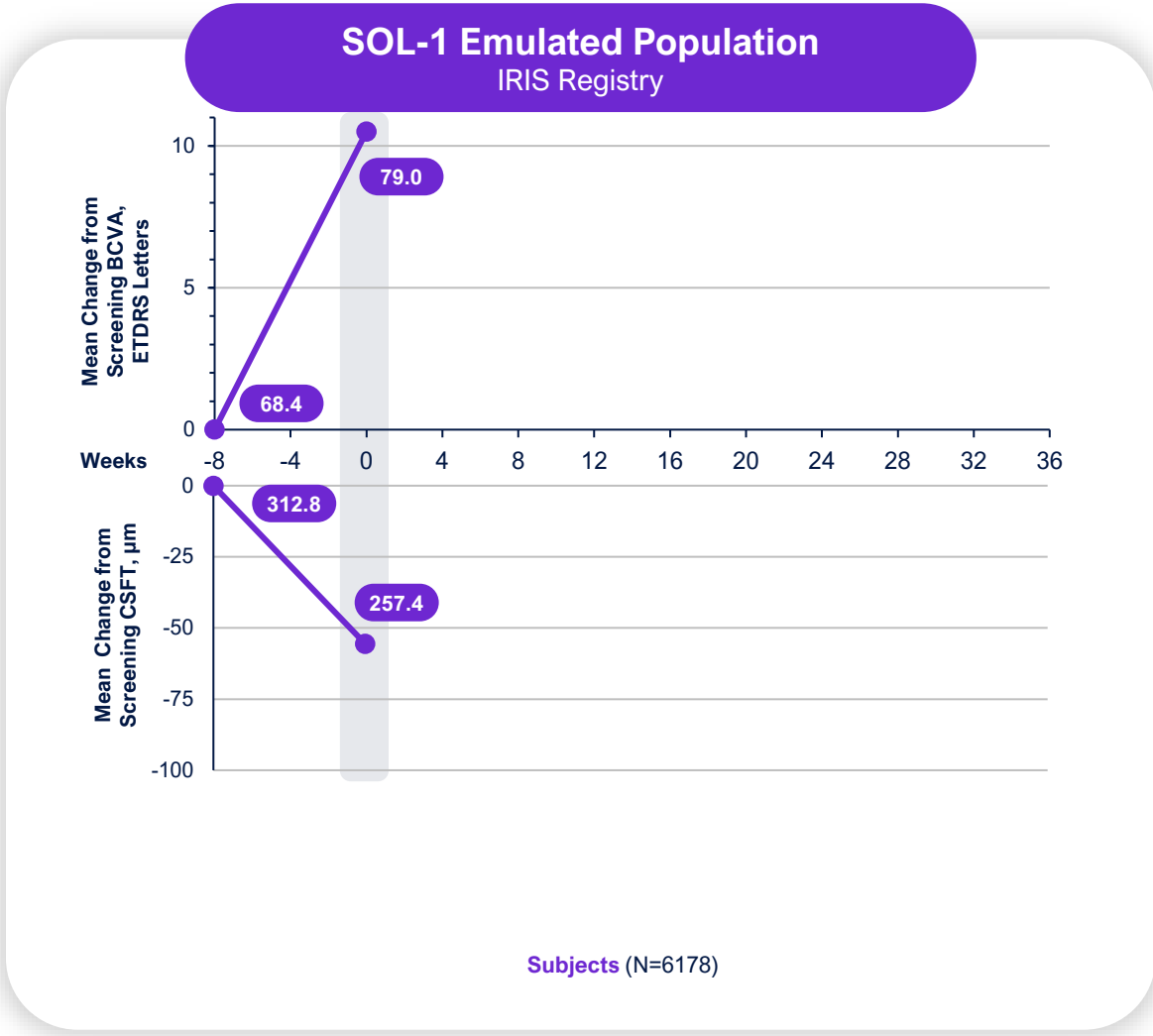
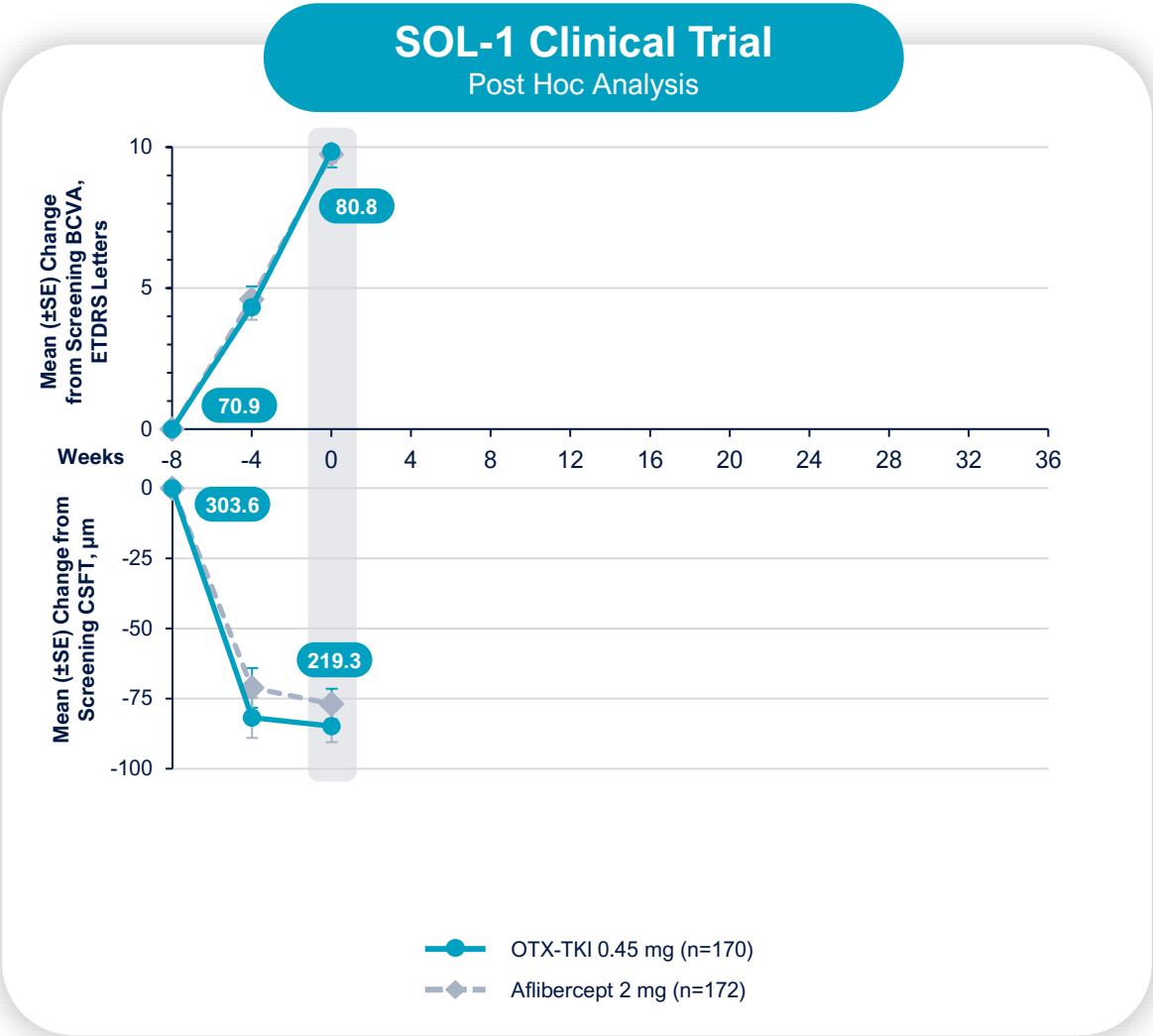
Contextualizing single-arm trials with real-world data: An emulated target trial comparing therapies for neovascular age-related macular degeneration

Darren S. Thomas¹ | Aaron Y. Lee² | Philipp L. Müller^{3,4,5} | Roy Schwartz^{4,5,6} | Abraham Olvera-Barrios^{4,5} | Alasdair N. Warwick^{4,7} | Praven J. Patel⁶ | Tjebo F.C. Heeren^{4,5} | Catherine Egan^{4,5,6} | Paul Taylor¹ | Adnan Tufail^{4,5,6} | on behalf of the UK AMD EMR Users Group⁷

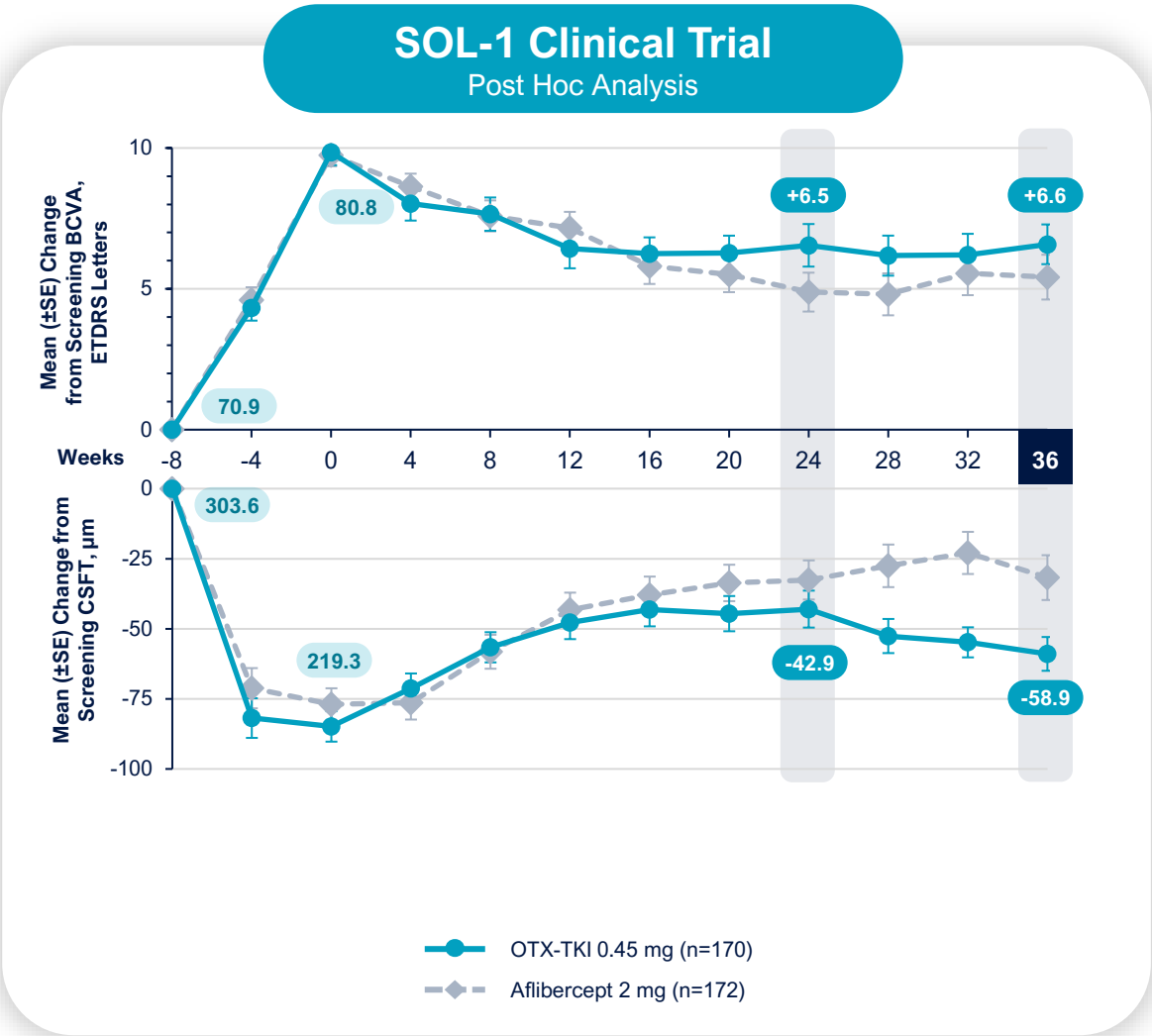
Using a similar methodology, we emulated SOL-1 entry criteria to the IRIS Registry



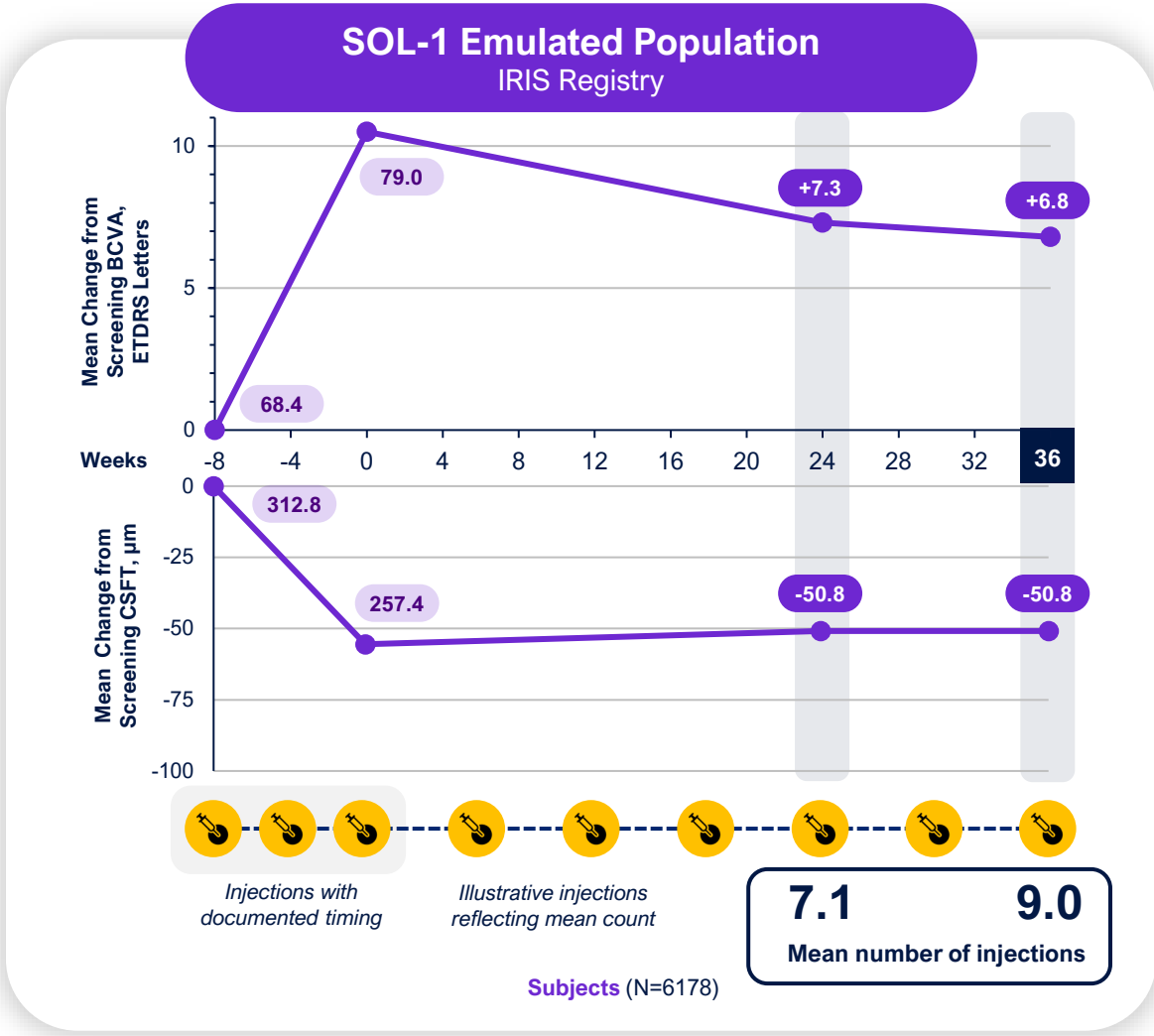
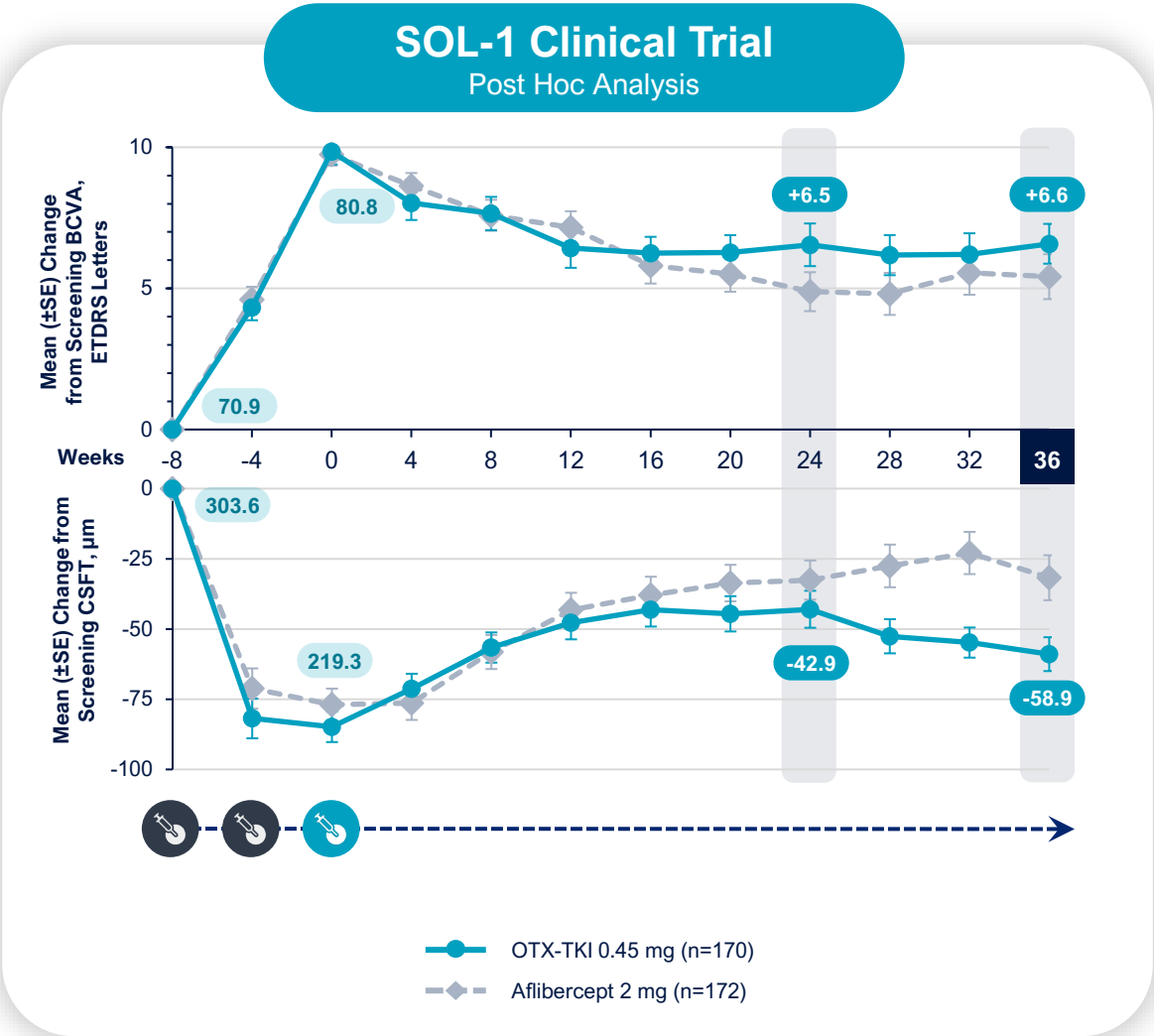
How Does SOL-1 Data Align with Real World Outcomes?



How Does SOL-1 Data Align with Real World Outcomes?

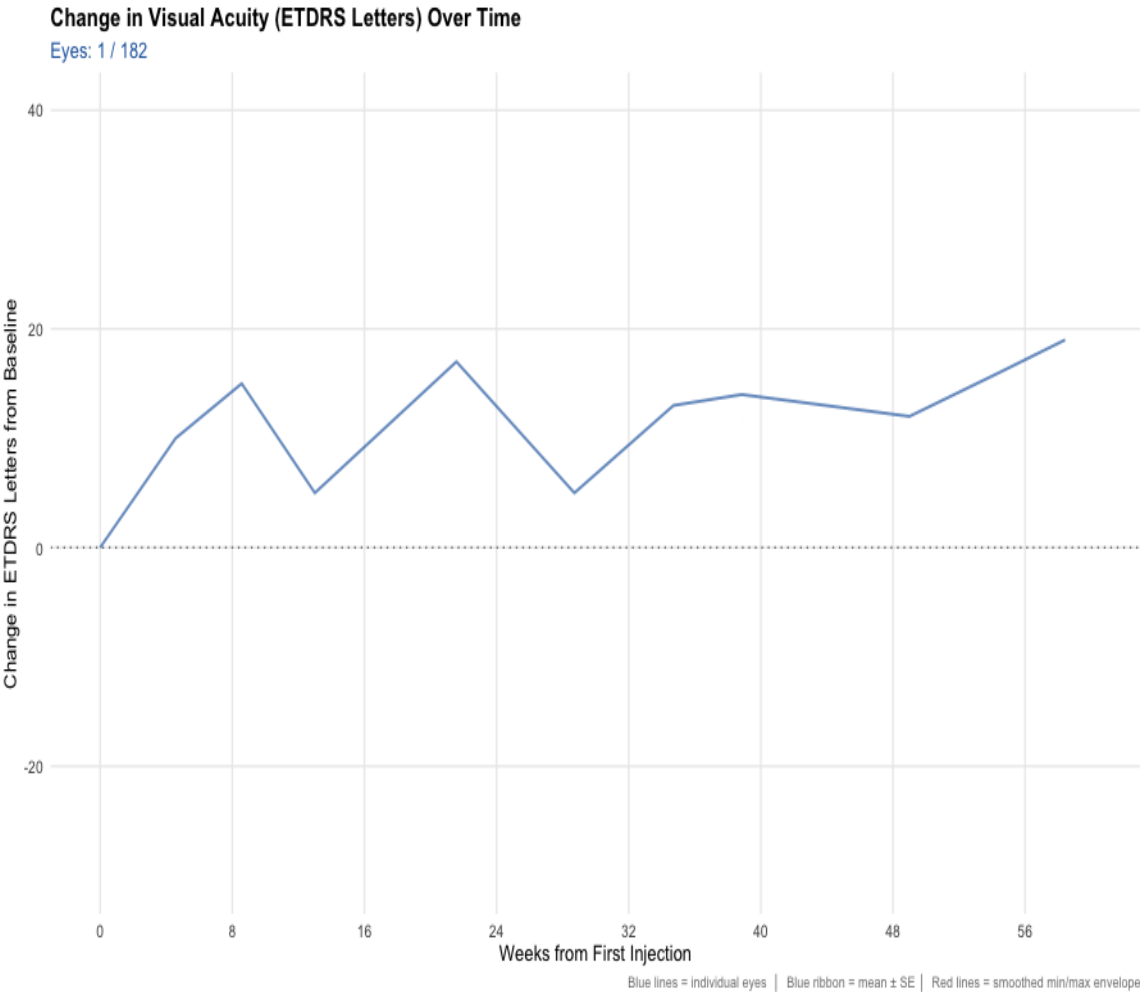
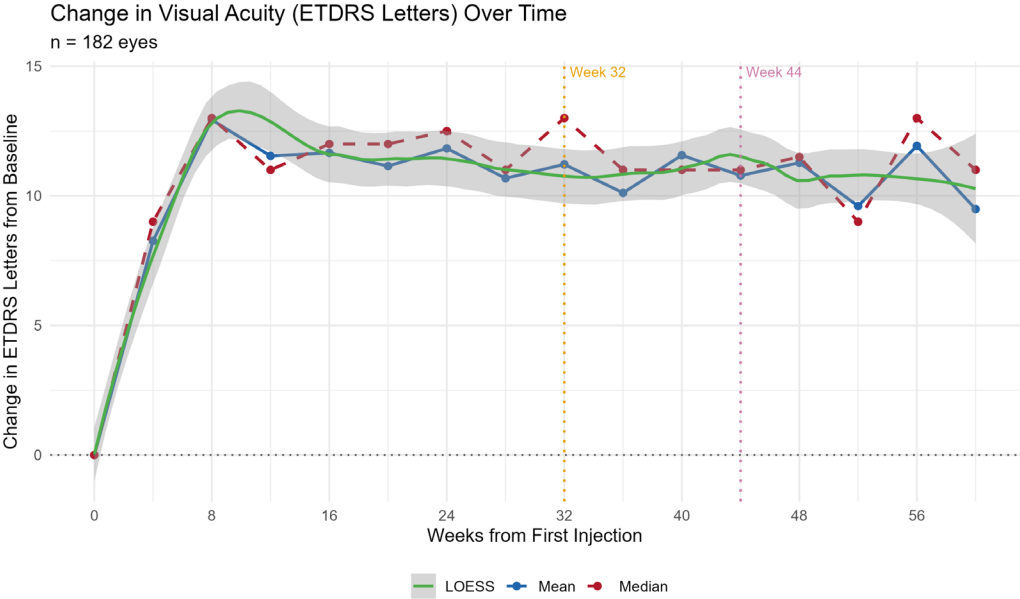


How Does SOL-1 Data Align with Real World Outcomes?



How Does SOL-1 Data Align with Real World Outcomes?

UK Dataset (2022 -2025)

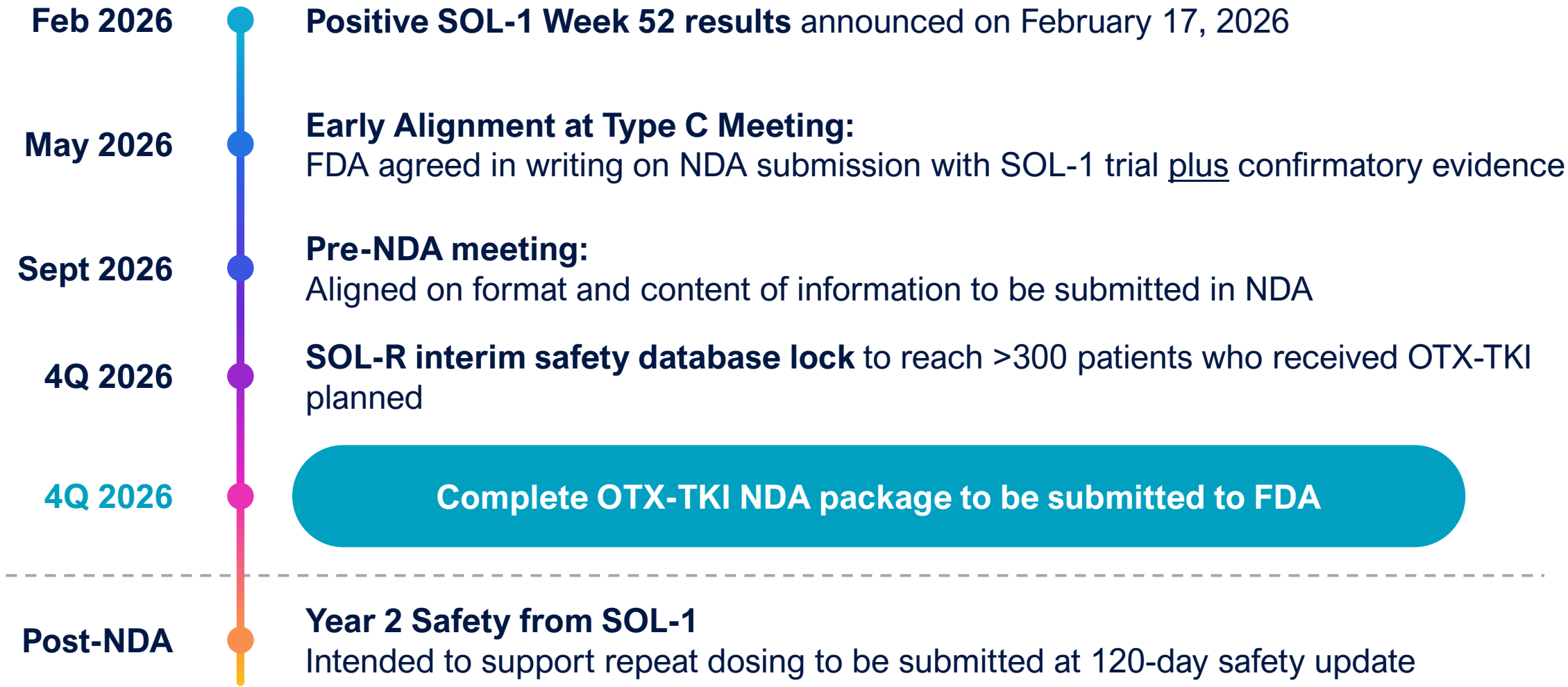


Age, mean = 78.9 years
Screen VA, mean = 65 letters
Baseline VA, mean = 78 letters

Clinical Program Update

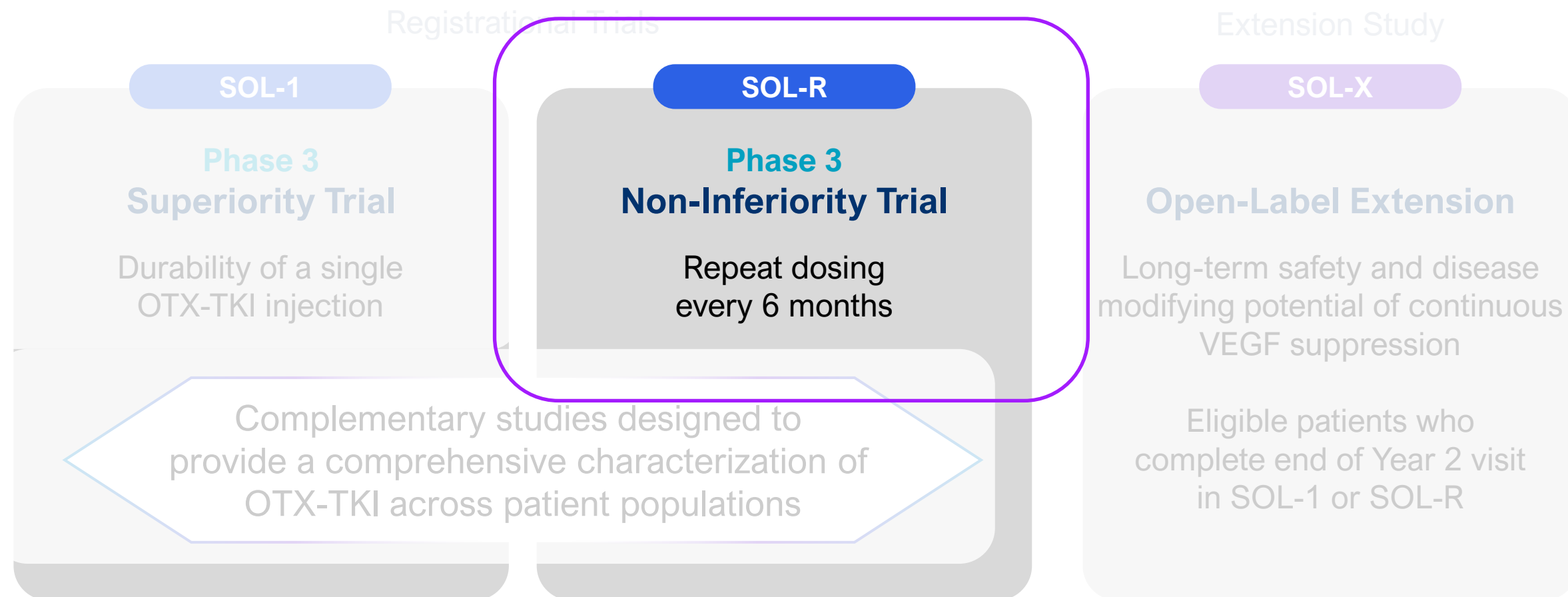
Arshad M. Khanani, MD, MA, FASRS

Timeline to OTX-TKI NDA Submission Package for nAMD

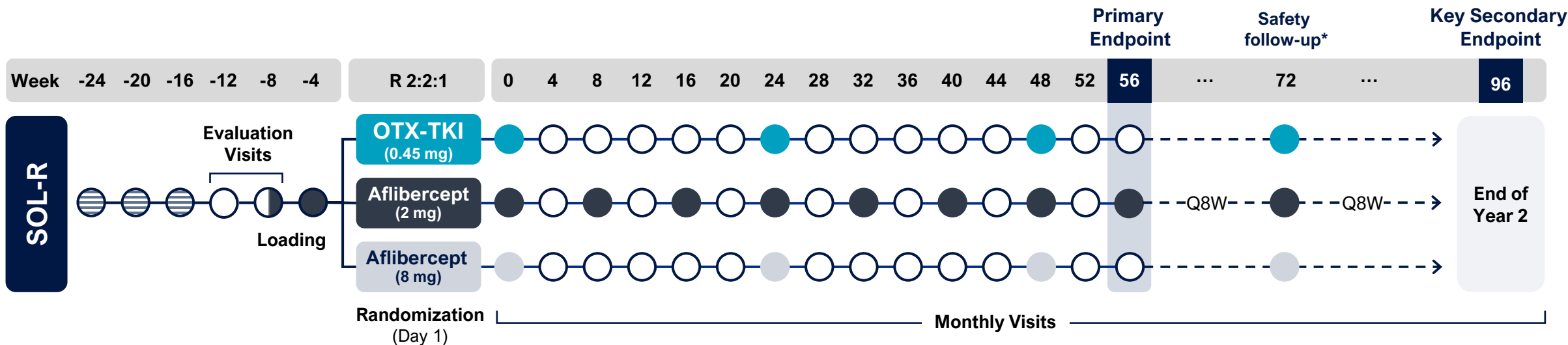


SOL: OTX-TKI Phase 3 Clinical Program in nAMD

Evaluating the efficacy, durability and safety of OTX-TKI in nAMD



SOL-R: Evaluation of with OTX-TKI relative to aflibercept 2 mg and 8 mg



Aflibercept 8mg dosing identical with no sham injections

Primary analysis:

OTX-TKI dosed Q24W vs.
aflibercept 2mg Q8W

Key Secondary Endpoint:

Superiority comparison at Year 2
vs. aflibercept 8mg

Secondary Endpoint:

Evaluating prevention of fibrosis
& atrophy vs. aflibercept 2mg

SOL: OTX-TKI Phase 3 Clinical Program in nAMD

Evaluating the efficacy, durability and safety of OTX-TKI in nAMD

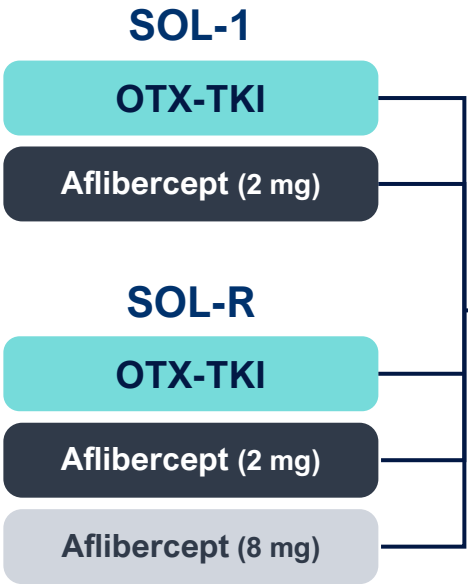


SOL-X: Unlocking Long-Term Value with OTX-TKI

Designed to evaluate safety and disease modifying potential of OTX-TKI

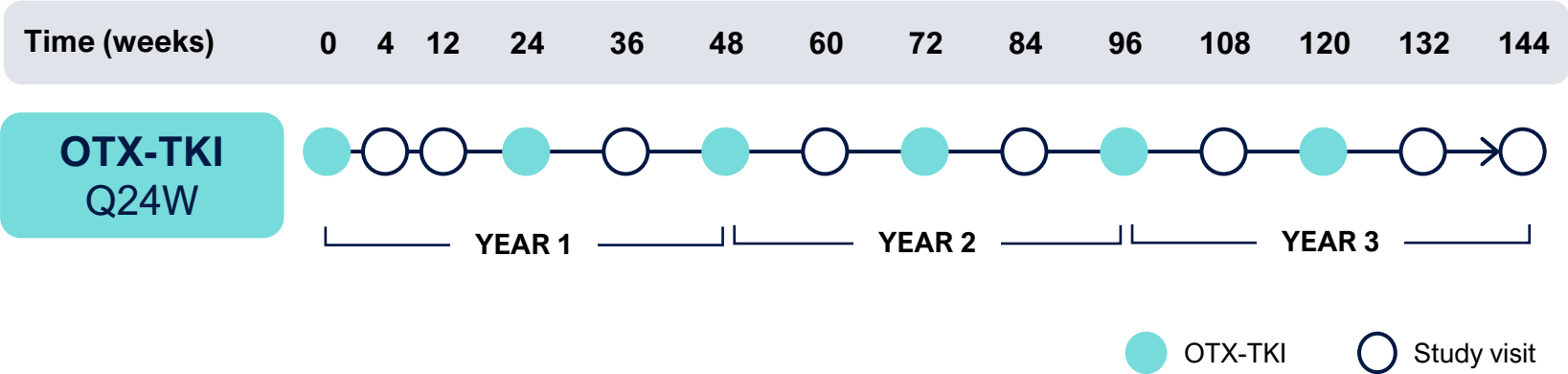
Primary Trials

Initial Treatment Arms



SOL-X

Three-year additional follow-up



Diabetic Retinopathy Program

HELIOS-3 Study Design



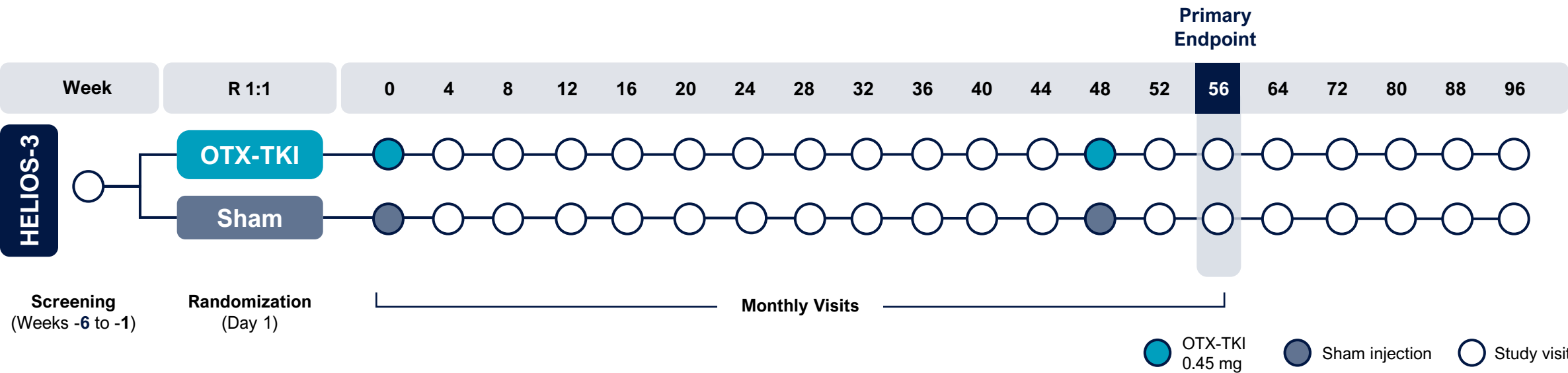
Evaluation of only Q12M OTX-TKI regimen vs Sham

Design

Superiority study of OTX-TKI in ~620 subjects with moderately-severe to severe NPDR without CI-DME

Primary Endpoint (Week 56)

Ordinal DRSS 2-step change status at **Week 56** from baseline (≥ 2 step improvement, ≥ 2 -step worsening, < 2 -step change in either direction)



OTX-TKI Development Program Summary

OTX-TKI

OTX-TKI demonstrated superior maintenance of vision* to aflibercept 2 mg at Week 36 in nAMD



nAMD Program

PHASE 3

Superiority Trial

Durability of a single OTX-TKI injection



Primary endpoint met

SOL-1

PHASE 3

Non-Inferiority Trial

Repeat dosing every 6 months

Randomization complete - topline data expected in Q1 '28

SOL-R

DR Program

PHASE 3

Superiority Trial

Evaluating yearly dosing

Enrollment in HELIOS-3 is underway

HELIOS-3

Panel Discussion

Moderated by
Arshad M. Khanani, MD, MA, FASRS

Faculty



Prof. Arshad M. Khanani
MD, MA, FASRS

Managing Partner, Director of Clinical Research, Director of Fellowship at Sierra Eye Associates, and Clinical Associate Professor at University of Nevada, Reno, NV, USA



Prof. Adnan Tufail
MBBS, MD, FRCOphth

Consultant Ophthalmic Surgeon at Moorfields Eye Hospital NHS Foundation, London, UK



Prof. Dilsher S. Dhoot
MD, FASRS

Adjunct Clinical Assistant Professor at Keck School of Medicine, University of Southern California and Vitreoretinal Specialist at California Retina Consultants Santa Barbara, CA, USA



Dr. Patricio G. Schlottmann
MD

Director of Research, Charles Ophthalmic Center and Ophthalmology Department Director at Organización Médica de Investigación, Buenos Aires, Argentina

Redefining the Management of nAMD

The Impact of Durability and Sustained Disease Control

October 2, 2026

Euretina | Vienna, Austria

