DAVIO 2 Phase 2 Trial: Vision Outcomes with Bioerodible EYP-1901 (vorolanib intravitreal insert) Versus Aflibercept in Wet Age-Related Macular Degeneration

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EYP-1901 (vorolanib intravitreal insert)

Sustained release of the potent and selective TKI vorolanib via bioerodible intravitreal drug delivery technology

Inhibits VEGFR, PDGFR, and IL-6 signaling

Therapeutic levels of vorolanib reached within hours[a]

No free-floating drug particles

Consistent daily dosing with target inhibition for ≥6 months

No cold storage required; pre-loaded IVT syringe injector

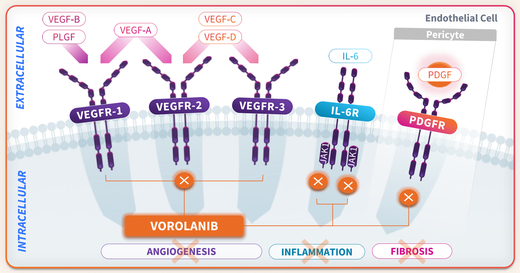
Each IVT insert is:
- **94% drug** / 6% matrix
- **1/5000th** of vitreous volume

Bioerodible
No PEG/PLGA
Drug release ≥6 months

Vorolanib

Potent and selective TKI working *intracellularly* to block pro-angiogenic and pro-inflammatory signaling

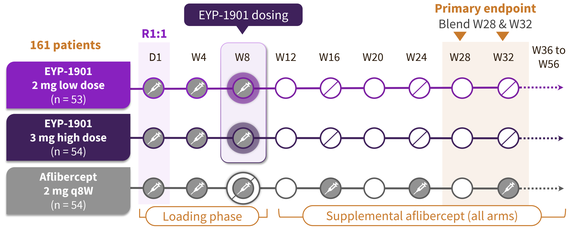
- Blocks signaling from all VEGFRs as well as PDGFR
- Inhibits IL-6 inflammatory signaling by targeting JAK1



The dose investigated in phase 3 trials is 2.7 mg (two inserts of 1.343 mg each) administered in a single injection.
[a] Data from preclinical studies. Following a single EYP-1901 900 µg dose in Dutch-Belted rabbits, vorolanib reached concentrations exceeding IC_{50} in the choroid and retina within hours of administration. Bakri SJ, et al. *PLoS One*. 2024;19(6):e0304782. Patel S, et al. *Ophthalmol Sci*. Sep-Oct 2024;4(5):100527. Wykoff CC, et al. *J Vitreoretin Dis*. Sep-Oct 2024;8(5):577-586. Singh RP, et al. Presentation at American Society of Retina Specialists (ASRS) Annual Meeting: July 28–August 1, 2023; Seattle, WA.

Phase 2 DAVIO 2 (NCT05381948) trial evaluated a single dose of EYP-1901 versus on-label aflibercept 2 mg q8W in patients with previously-treated wet AMD

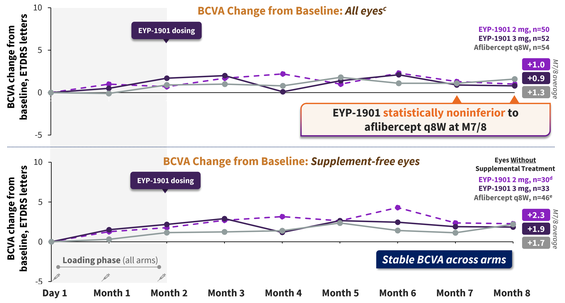
Study Design



Protocol prespecified criteria[a]
BCVA reduction ≥5 letters and CST increase ≥75 µm **OR** Vision threatening hemorrhage **OR** BCVA reduction ≥10 letters **OR** CST increase ≥100 µm on 2 consecutive visits
Investigator discretion

[a] Due to wet AMD; from best on-study measurement.

Primary Endpoint Met



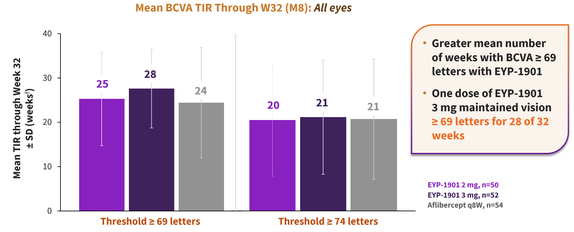
[c] Full analysis population. [d] Supplemental treatment subgroup analysis excludes 1 patient who discontinued before Week 12 and 1 patient who received supplemental treatment at an unscheduled visit. *Including injections where aflibercept q8W patients met supplemental treatment criteria on scheduled q8W aflibercept injection visits.

BCVA Time In Range

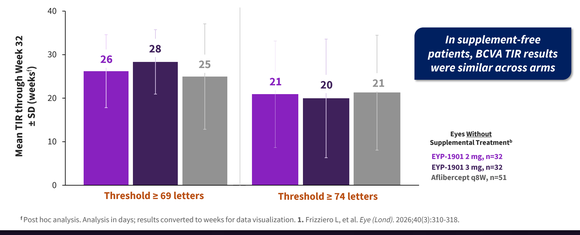
- Traditional BCVA measurements at fixed timepoints do not capture fluctuations over time[1]
- Higher TIR reflects greater duration of time with vision at or above a clinically relevant threshold[1]

Post Hoc TIR Analysis
- Defined as the **cumulative duration in days between visits during which absolute BCVA remained at or above the threshold**
- All BCVA results through W32 included

Selected TIR Thresholds
- **≥ 69 letters** (~20/40 SE, minimum driving requirement in the UK and most US states)
- **≥ 74 letters** (study baseline mean)



- **Greater mean number of weeks with BCVA ≥ 69 letters with EYP-1901**
- **One dose of EYP-1901 3 mg maintained vision ≥ 69 letters for 28 of 32 weeks**



[f] Post hoc analysis. Analysis in days; results converted to weeks for data visualization. **1.** Frizziero L, et al. *Eye (Lond)*. 2026;40(3):310-318.

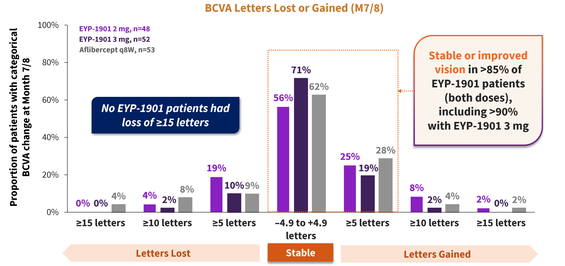
Baseline Characteristics

Baseline characteristics were well-balanced between arms

~10 anti-VEGF injections in past year *normalized mean;*[b] *range 2–13 injections*	**~20/32 Snellen equivalent** *mean 73–75 ETDRS letter score; range, 41–85 letters*
~2 years since diagnosis *mean; range, 0.1–20 years*	**~263–266 µm CST** *mean; range, 178–400 µm*

[b] Normalized to a 12-month treatment period: Number of actual injections received divided by actual months of prior treatment and multiplied by 12 months. Range reflects actual injections received.

Stable Vision with EYP-1901



Stable or improved vision in >85% of EYP-1901 patients (both doses), including >90% with EYP-1901 3 mg

Patients with ±10- or ±15-letter changes are included within the percentages for ±5-letter change.

EYP-1901 was Well-Tolerated

- No EYP-1901–related ocular or systemic SAEs
- No insert migration into the anterior chamber
- No cases of retinal occlusive vasculitis
- No discontinuations related to EYP-1901 treatment

Key Takeaways

- Mean BCVA change with EYP-1901 **statistically noninferior** vs aflibercept q8W
- **>85%** of EYP-1901 patients had **stable or improved vision**
- EYP-1901 patients maintained **similar TIR** compared to aflibercept q8W

Phase 3 Program Ongoing

Topline data from trials assessing EYP-1901 with 6-month redosing expected mid-2026 for **LUGANO** (NCT06668064), with **LUCIA** (NCT06683742) to follow

Presented at the Royal College of Ophthalmology (RCOphth) Meeting
May 18-21, 2026 | Manchester, UK
Please visit eyepoint.bio for more information

Study Disclosures
EYP-1901 is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain. These data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled phase 3 clinical trials. Funding was provided by EyePoint for the study and third-party writing support by Nancy Nguyen, PharmD, of Koahana, Inc.

Author Disclosures
Christiana Dinah: Apellis, Roche, Topcon (institutional grants); AbbVie, Alimera Sciences, Apellis, Astellas, Bayer, Boehringer Ingelheim, EyePoint, Johnson and Johnson, Ocular Therapeutix, Roche (advisory boards and consulting); AbbVie, Apellis, Bayer, Boehringer Ingelheim, Roche, Topcon (speaker fees); **Ramiro Ribeiro:** EyePoint (employee).

Abbreviations
AMD, age-related macular degeneration; **BCVA**, best-corrected visual acuity; **CST**, central subfield thickness; **D**, day; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **IL-6(R)**, interleukin-6 (receptor); **IVT**, intravitreal; **JAK**, Janus kinase; **M,** month; **PEG**, polyethylene glycol; **PDGF(R)**, platelet-derived growth factor (receptor); **PLGA**, poly lactic-co-glycolic acid; **PLGF**, placental growth factor; **q8W**, every 8 weeks; **R**, randomization; **SAE**, serious adverse event; **SE**, Snellen equivalent; **TIR**, time in range; **TKI**, tyrosine kinase inhibitor; **VEGF(R)**, vascular endothelial growth factor (receptor); **W**, week.