EYP-1901 for Wet Age-Related Macular Degeneration: Key Learnings From DAVIO 2 and the Clinical Trial Program

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Disclosures

EYP-1901 is an investigational product and the safety and efficacy of EYP-1901 has not been established. FDA has not approved EYP-1901 in the United States. The materials discussed in this presentation do not predict future FDA approval. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Disclosures

Presenter Disclosures

- Consultant: Genentech, Bausch+Lomb, EyePoint
- Advisory board: Genentech, Abbvie, Apellis, Iveric Bio

Study Disclosures

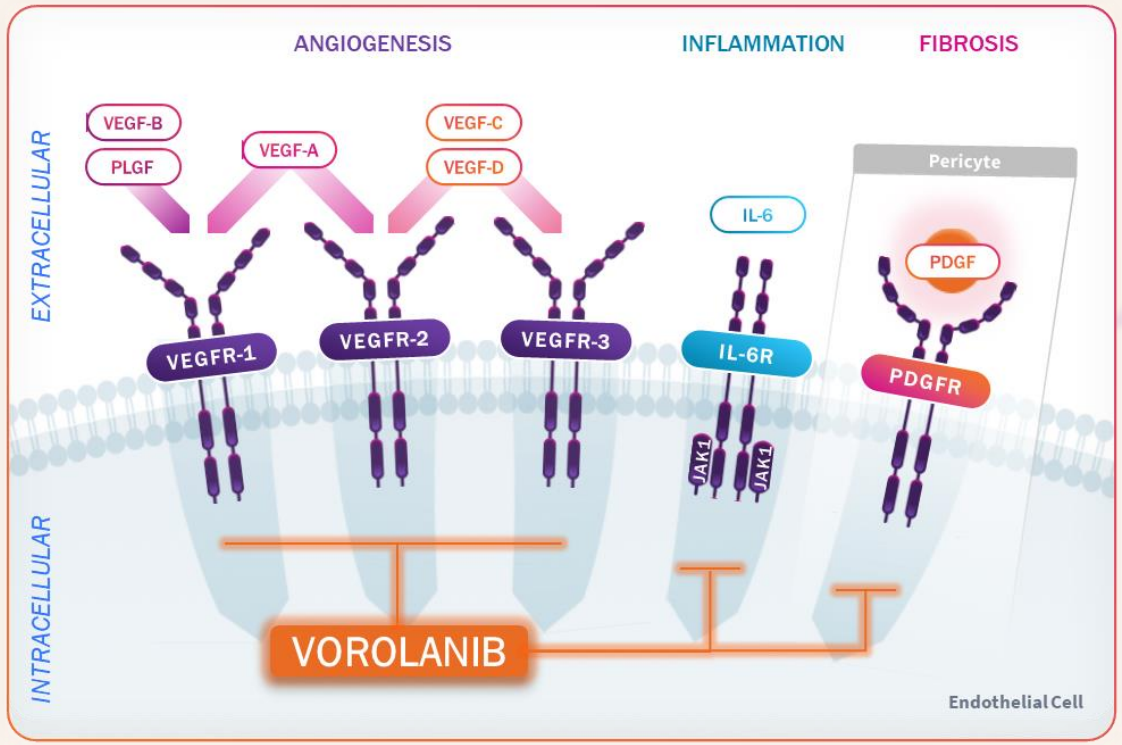
- Funding was provided by EyePoint for the study and third-party writing support by Nancy Nguyen, PharmD, of Koahana, Inc.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

EYP-1901 (vorolanib intravitreal insert) is Designed to Provide Sustained Release of the TKI Vorolanib for at least 6 Months[1-5]

Vorolanib Multi-MoA[1-2]

Inhibition of **VEGFR**, **PDGFR**, and **IL-6** signaling in nonclinical studies



Each bioerodible IVT insert is:

- **94% drug** / 6% matrix
- **1/5000th** of vitreous volume

No PEG/PLGA

Drug release ≥6 months

- Therapeutic levels of vorolanib reached **within hours**[a]
- **No free-floating drug** particles

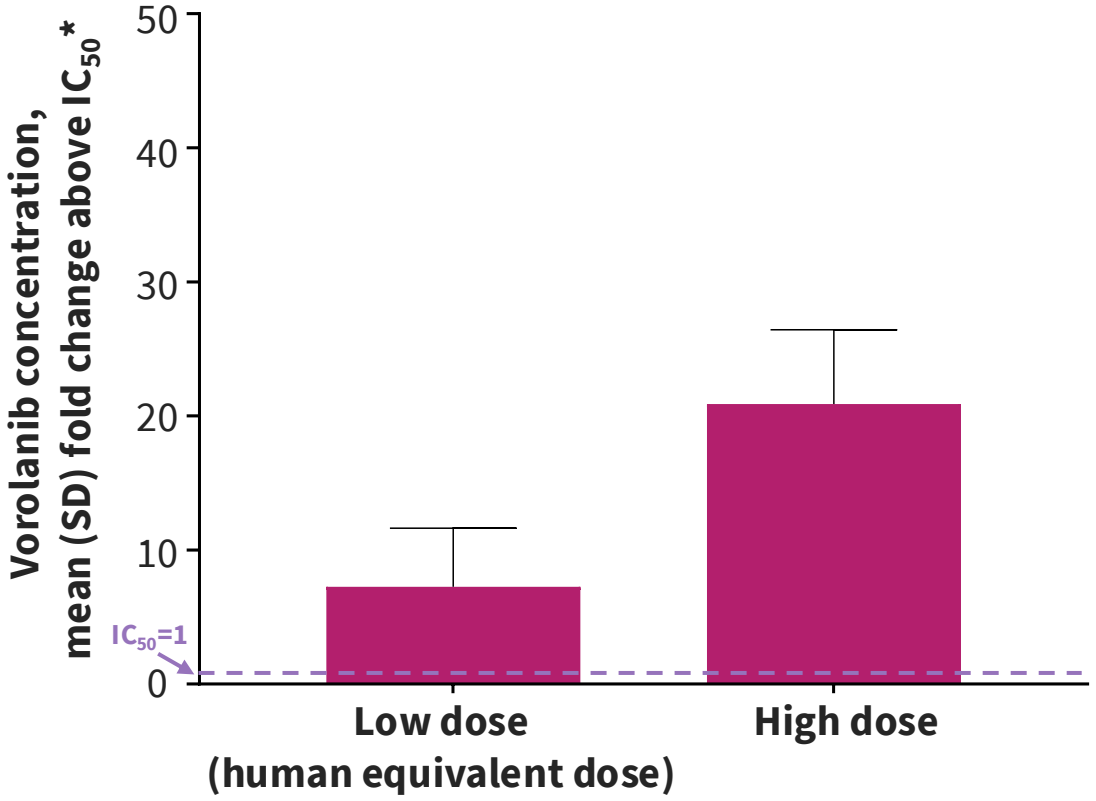
The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] Data from preclinical studies. Following a single injection of EYP-1901 in Dutch-Belted rabbits, vorolanib reached concentrations exceeding IC_{50} in the retina and RPE within 8 hours.[3]

1. Bakri SJ, et al. *PLoS One.* 2024;19(6):e0304782. **2.** Singh RP, et al. Presentation at ARVO: May 3–7, 2026; Denver, CO. **3.** Lynch J, et al. Presentation at ARVO: May 3–7, 2026; Denver, CO. **4.** Patel S, et al. *Ophthalmol Sci.* Sep-Oct 2024;4(5):100527. **5.** Wykoff CC, et al. *J Vitreoretin Dis*. 2024 Aug 22;8(5):577-586. **IL-6(R)**, interleukin-6 (receptor); **IVT**, intravitreal; **JAK**, Janus kinase; **MOA**, mechanism of action; **PEG**, polyethylene glycol; **PDGF(R)**, platelet-derived growth factor (receptor); **PLGA**, poly lactic-co-glycolic acid; **PLGF**, placental growth factor; **RPE**, retinal pigment epithelium; **TKI**, tyrosine kinase inhibitor; **VEGF(R)**, vascular endothelial growth factor (receptor).

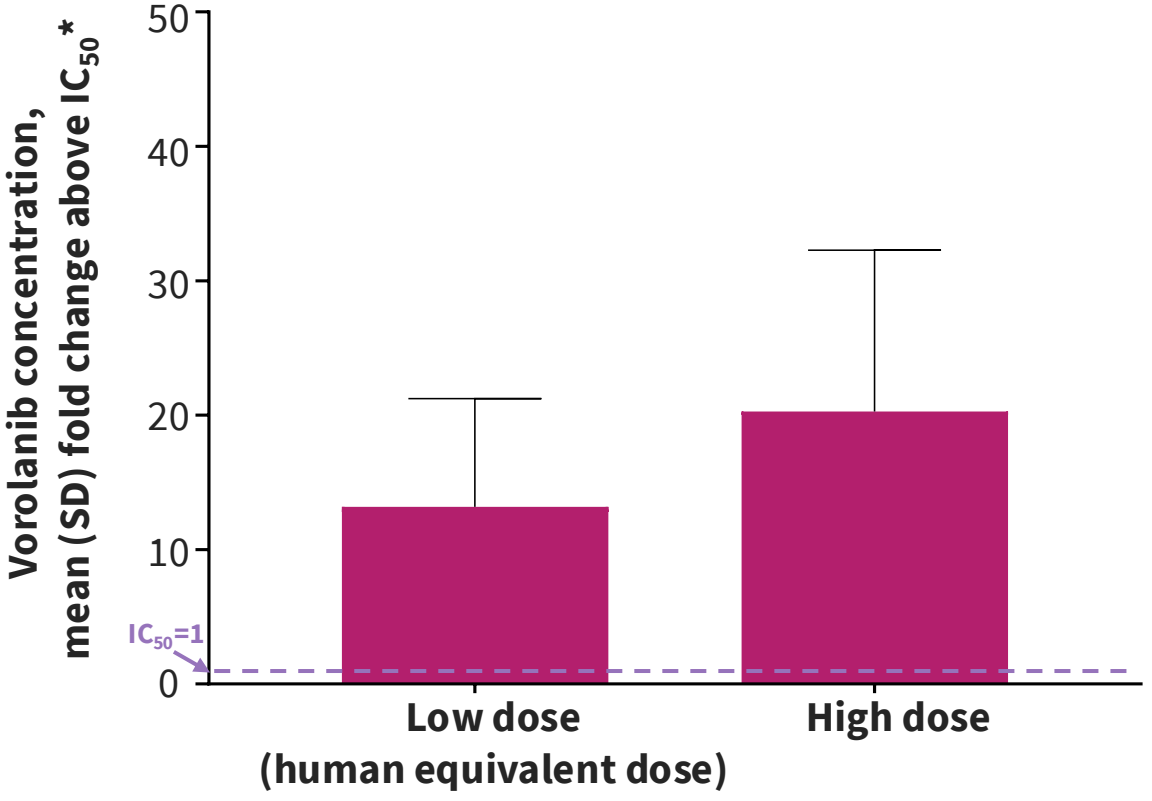
Data on file. These data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled phase 3 clinical trials.

Vorolanib Concentrations Above Target Inhibitory Levels 8 hours After Injection with Phase 3 Inserts in Nonclinical Studies

Vorolanib Concentration in Retina at 8 Hrs with Phase 3 Inserts in Rabbits



Vorolanib Concentration in RPE at 8 Hrs with Phase 3 Inserts in Rabbits

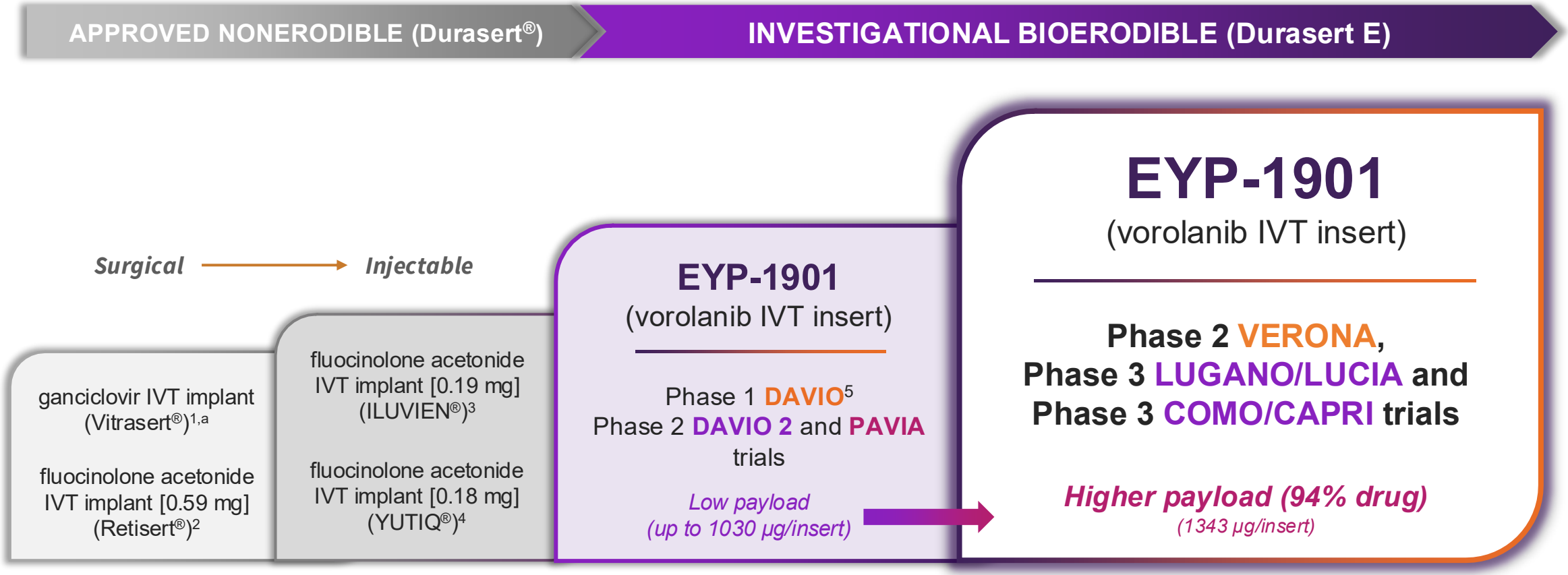


Vorolanib concentration in the target tissues 8 hours after administration of phase 3 inserts presented as fold change above average IC_{50}.

The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. *Blended IC50 for VEGFR-2, PDGFR, and JAK1. Lynch J, et al. Presentation at The Associate for Research in Vision and Ophthalmology (ARVO) Annual Meeting: May 3–7, 202; Denver, CO. **RPE,** retinal pigment epithelium. ClinicalTrials.gov identifiers: Phase 2 DAVIO 2 NCT05381948; Phase 3 LUGANO NCT06668064 and LUCIA NCT06683742.

Data on file. These data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled phase 3 clinical trials.

EYP-1901 was Developed Following Over 3 Decades of Innovation in Sustained-Release Drug Delivery for Retinal Disease

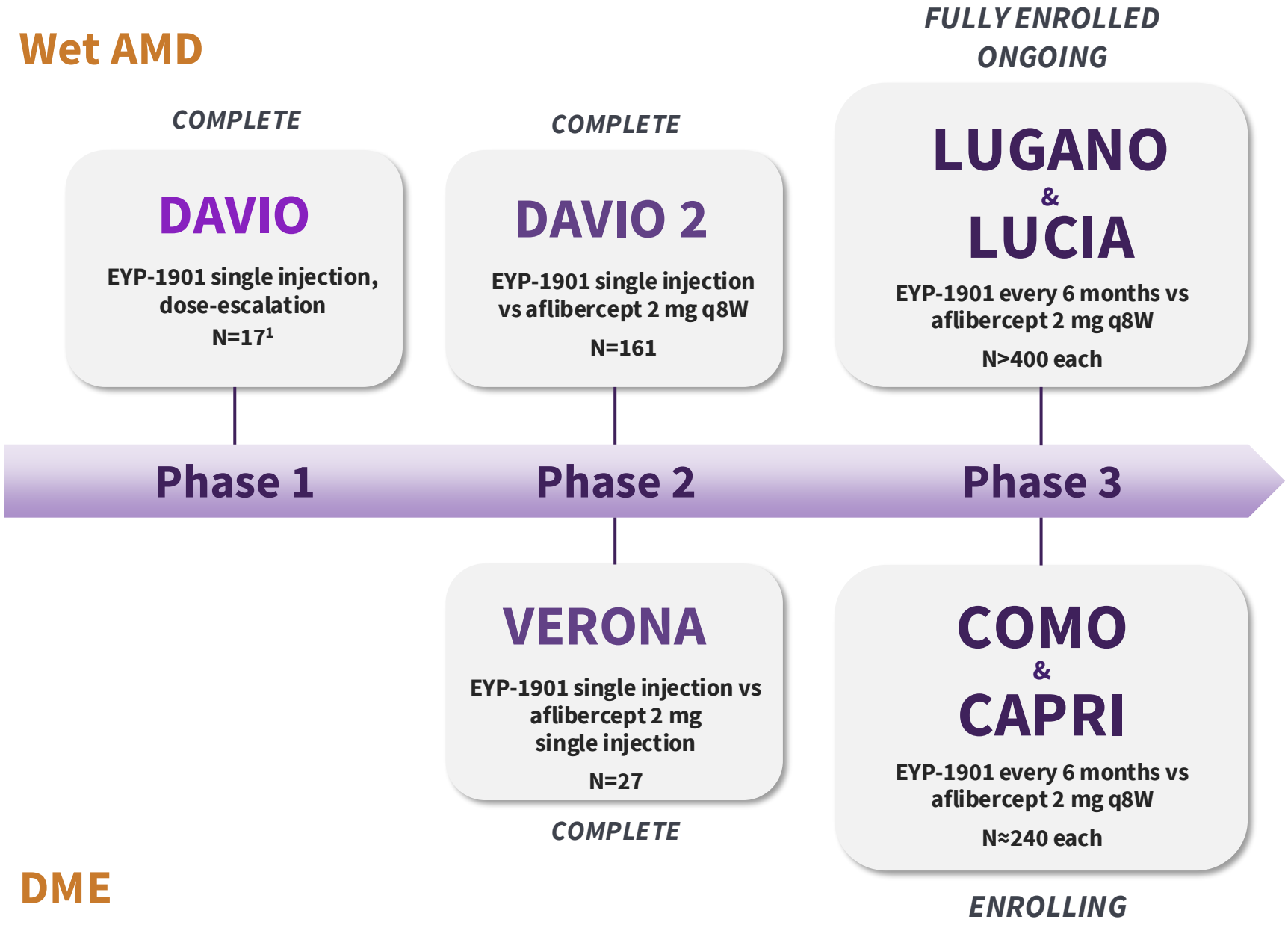


The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] Vitrasert now discontinued. **1.** Wykoff CC, et al. J Vitreoretin Dis. 2024;8(5):577–86. **2.** Bausch and Lomb (2025). RETISERT (fluocinolone acetonide intravitreal implant). [Available at: Prescribing Information - RETISERT]. **3.** Alimera Sciences (2016). ILUVIEN® (fluocinolone acetonide intravitreal implant). [Available at: Prescribing Information – ILUVIEN]. **4.** Alimera Sciences (2023). YUTIQ® (fluocinolone acetonide intravitreal implant). [Available at: Prescribing Information - YUTIQ]. **5.** Patel S, et al. Ophthalmol Sci. 2024;4(5):100527. **IVT,** intravitreal.
ClinicalTrials.gov identifiers: DAVIO NCT04747197; DAVIO 2 NCT05381948; PAVIA NCT05383209; VERONA NCT06099184; LUGANO NCT06668064; LUCIA NCT06683742; COMO, NCT07449936; CAPRI, NCT07449923.

EYP-1901 Data on file. These EYP-1901 data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled phase 3 clinical trials.

Clinical Trials for EYP-1901 in Wet AMD and DME

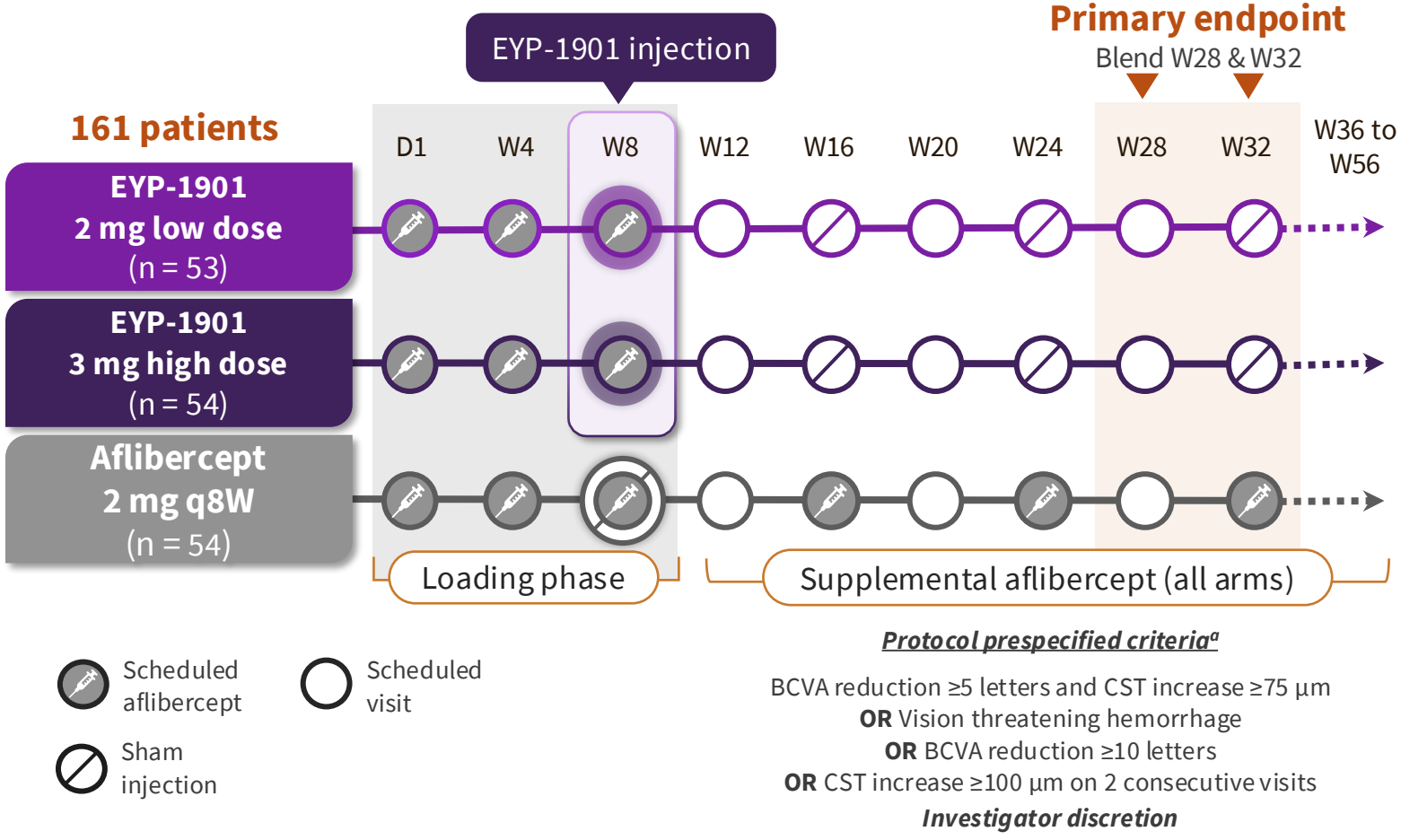
Building evidence for EYP-1901 with the largest sustained-release TKI clinical trial program for wet AMD and DME



The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. **1.** Patel S, et al. *Ophthalmol Sci.* 2024;4(5):100527. **AMD**, age-related macular degeneration; **DME**, diabetic macular edema; **q8W**, every 8 weeks; **SoC**, standard of care; **TKI,** tyrosine kinase inhibitor. Clinicaltrial.gov identifiers: COMO, NCT07449936; CAPRI, NCT07449923. DAVIO, NCT04747197; DAVIO 2, NCT05381948; LUGANO, NCT06668064; LUCIA, NCT06683742; VERONA, NCT06099184.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

DAVIO 2: Phase 2 Trial of EYP-1901 vs On-Label Aflibercept 2 mg q8W in Previously-Treated Wet AMD



Primary endpoint

- **Mean change in BCVA at Months 7 and 8, averaged (6 months after EYP-1901 dose)**

DAVIO 2 enrolled previously-treated patients[b]

~20/32 Snellen equivalent

(mean 73–75 ETDRS letters; range 41–85 letters)

~263–266 µm CST

(mean; range, 178–400 µm)

~10 anti-VEGF injections/year prior to study entry[c]

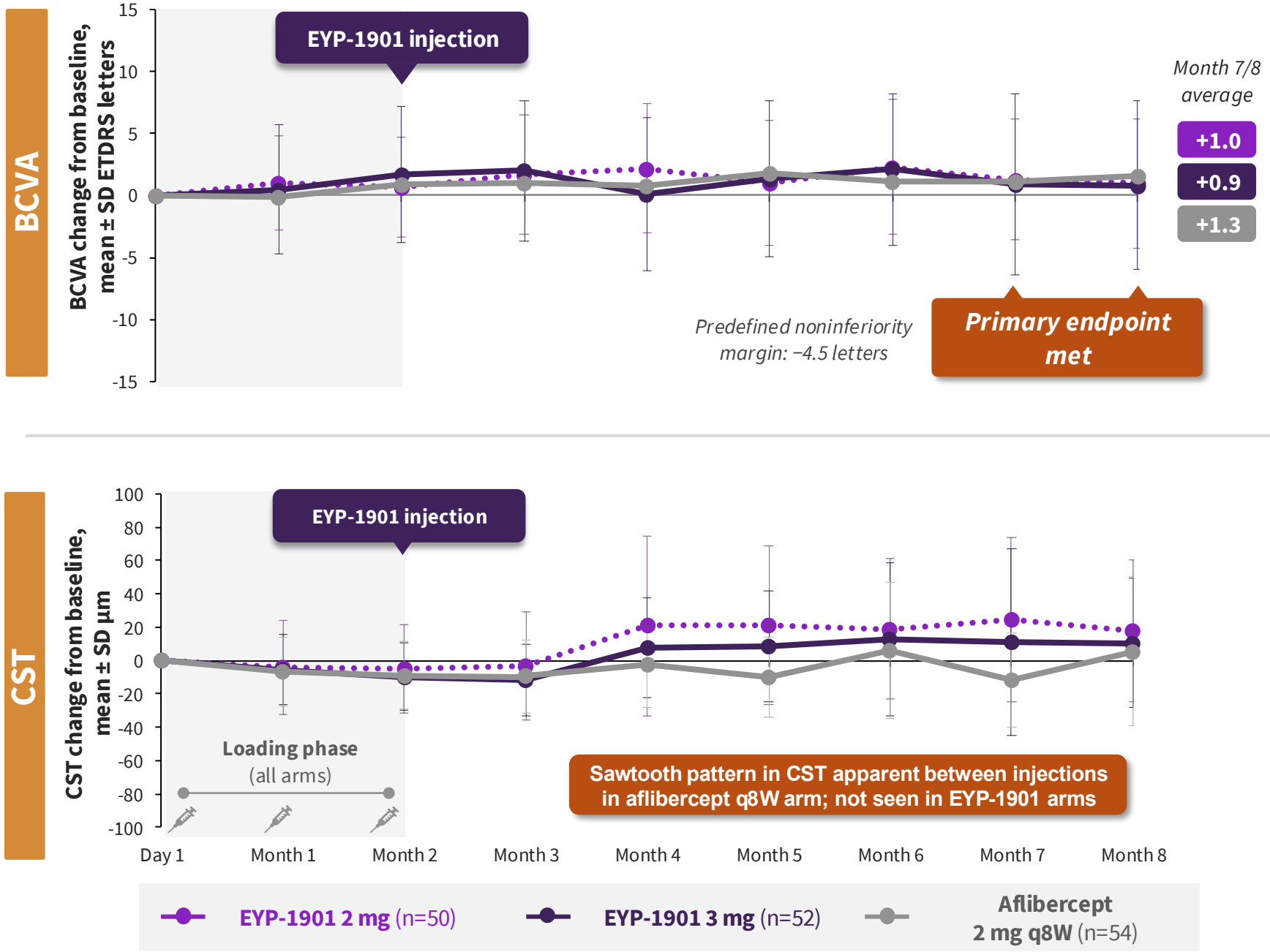
[a] Due to wet AMD; from best on-study measurement. [b] Values reflect baseline characteristics of Full Analysis Set (n=156), defined as patients who received both Day 1 and Week 8 treatments. [c] Normalized mean; range 2–13 injections. Normalized to a 12-month treatment period: number of actual injections received divided by actual months of prior treatment and multiplied by 12 months. **AMD,** age-related macular degeneration; **BCVA,** best-corrected visual acuity; **CST,** central subfield thickness; **D,** day; **IVT,** intravitreal; **q8W,** every 8 weeks; **VEGF,** vascular endothelial growth factor; **W,** week. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Primary Endpoint Met

BCVA statistically noninferior with a *single* EYP-1901 dose vs aflibercept 2 mg q8W

- Stable vision and CST with a single EYP-1901 dose



BCVA, best-corrected visual acuity; **CST,** central subfield thickness; **ETDRS,** Early Treatment Diabetic Retinopathy Study; **q8W,** every 8 weeks. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Subgroup Analysis • Supplement-Free Eyes

Supplemental Injections Did Not Drive BCVA Outcomes

All eyes[a]

EYP-1901 2 mg, n=50

EYP-1901 3 mg, n=52

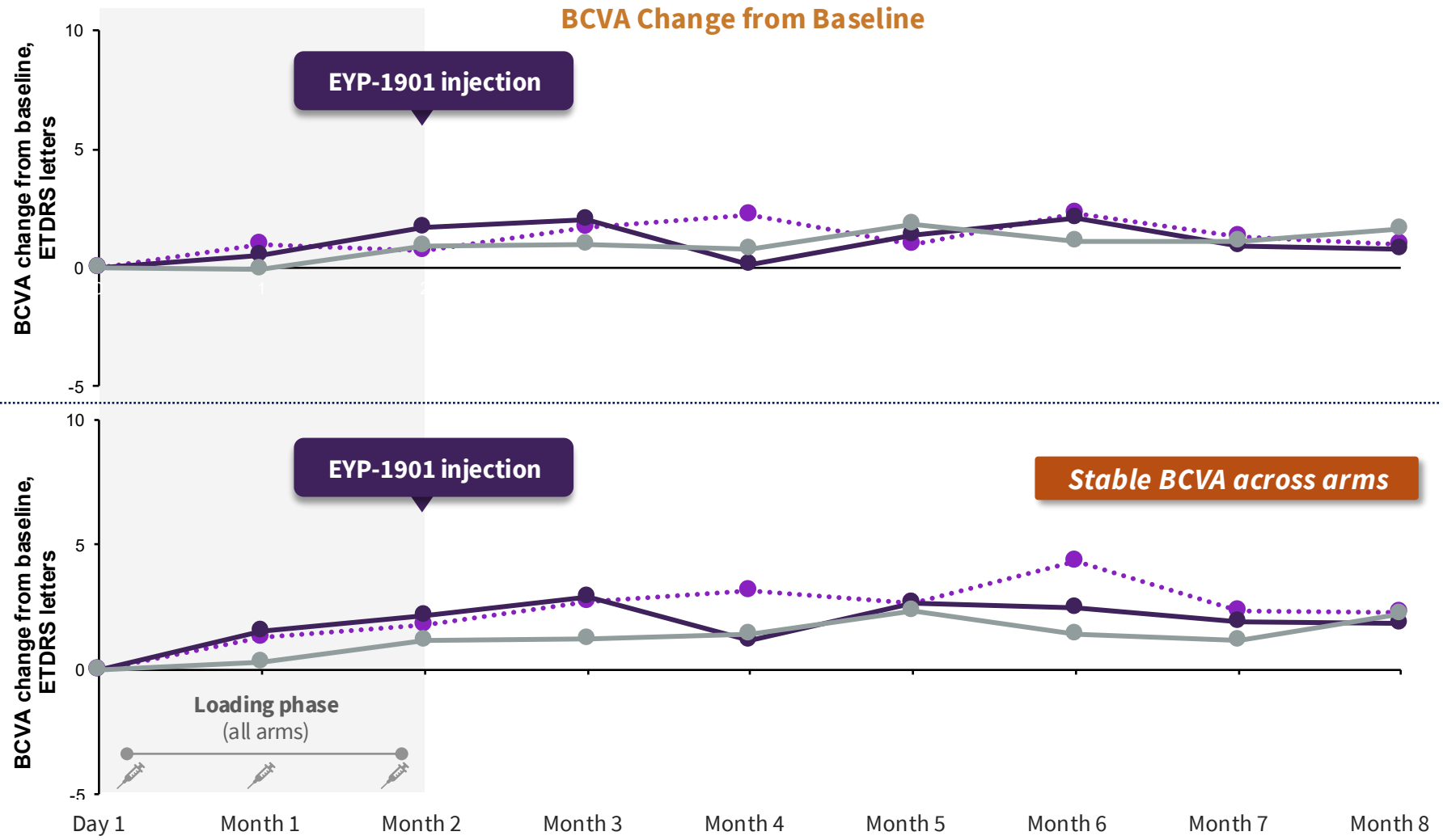
Aflibercept 2 mg q8W, n=54

Eyes *without* supplemental treatment

EYP-1901 2 mg, n=30[b]

EYP-1901 3 mg, n=33

Aflibercept 2 mg q8W, n=46[c]

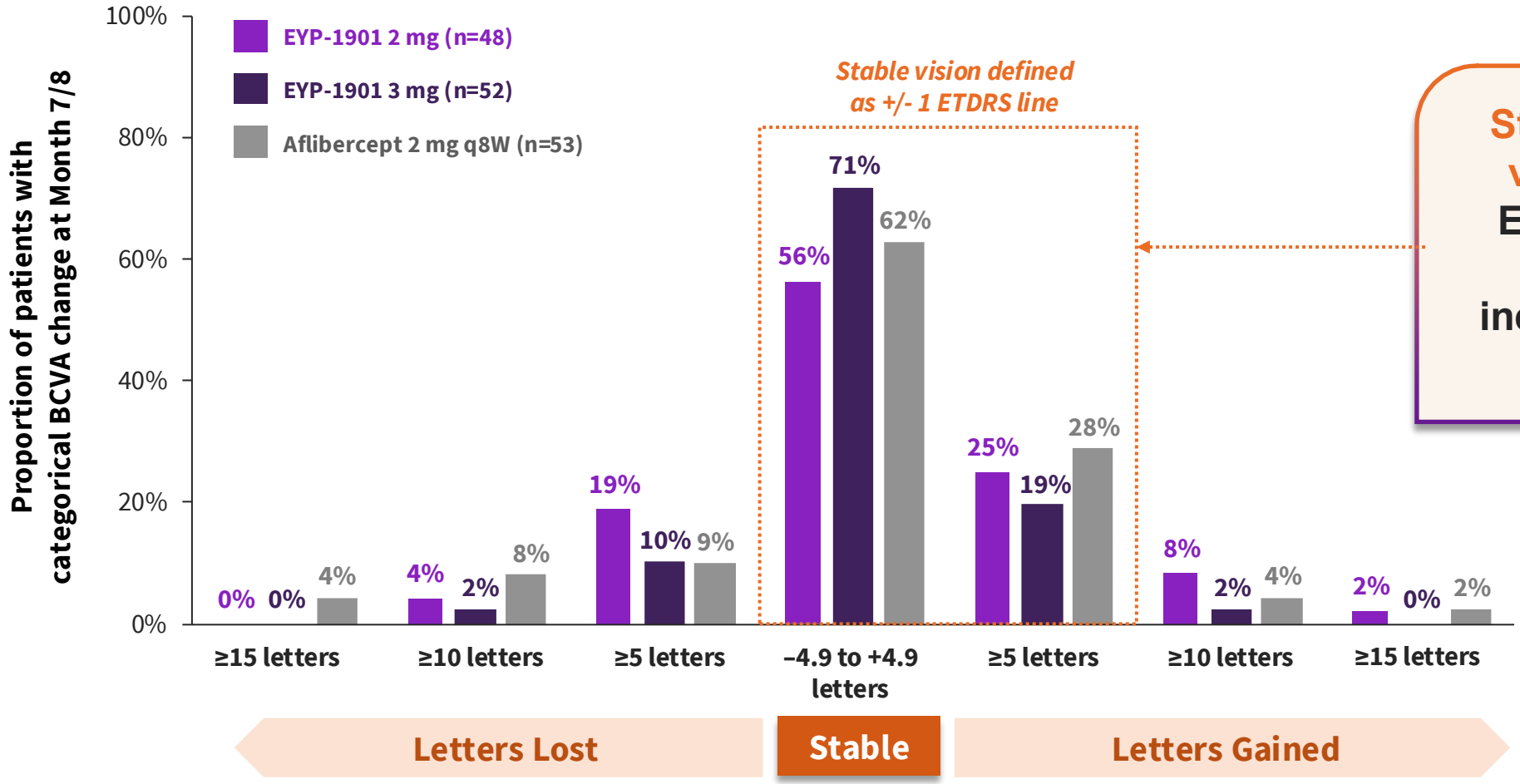


Post hoc analysis. [a] Full analysis population. [b] Supplemental treatment subgroup analysis excludes 1 patient who discontinued before Week 12 and 1 patient who received supplemental treatment at an unscheduled visit. [c] Including injections where aflibercept q8W arm patients met supplemental treatment criteria on scheduled q8W aflibercept injection visits. **AMD,** age-related macular degeneration; **BCVA,** best-corrected visual acuity; **ETDRS,** Early Treatment Diabetic Retinopathy Study; **q8W,** every 8 weeks.
DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Stable or Improved Vision in >90% of Patients with EYP-1901 3 mg

BCVA Letters Lost or Gained (Month 7/8)



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. **BCVA,** best-corrected visual acuity; **q8W,** every 8 weeks. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Fewer EYP-1901–Treated Eyes Had Significant Vision Loss Compared with On-Label Aflibercept 2 mg q8W

Patients with BCVA outcome at Month 7/8, n (%)	EYP-1901 (n=100; doses pooled)	Aflibercept 2 mg q8W (n=53)
≥10 Letters Lost	3 (3%)	4 (7.5%)
≥15 Letters Lost	0	2 (3.8%)

No EYP-1901–treated eyes had loss ≥15 letters

Patients with ≥10- or ≥15-letter changes are included within the percentages for ≥5-letter change. **BCVA,** best-corrected visual acuity; **q8W,** every 8 weeks. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

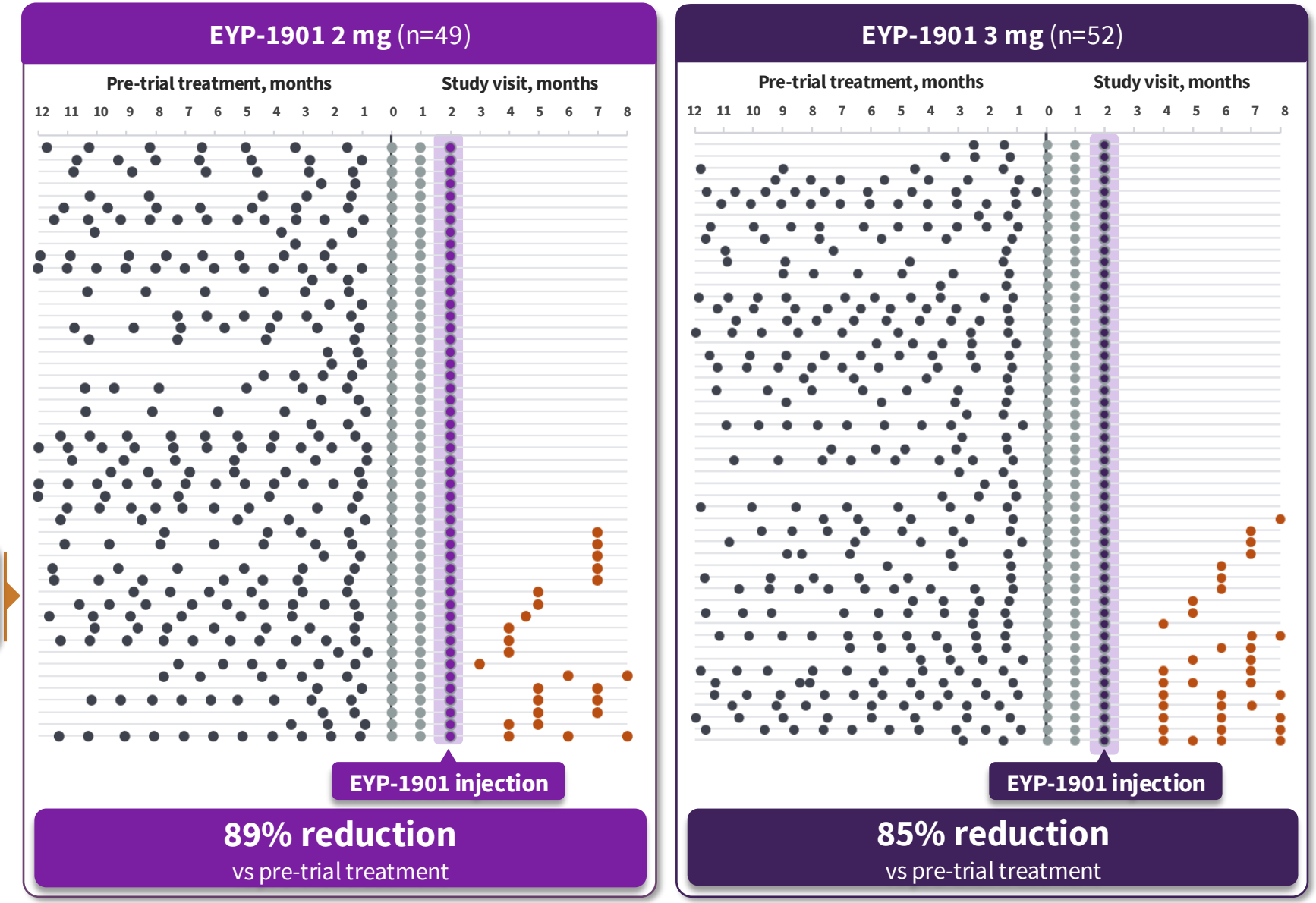
Individual Treatment

≥85% overall reduction in treatment burden with a single dose of EYP-1901 vs pre-trial

Each row represents treatment experience of one patient

Overall treatment experience per patient

Pre-trial anti-VEGF | Scheduled aflibercept | EYP-1901 + scheduled aflibercept | Supplemental aflibercept



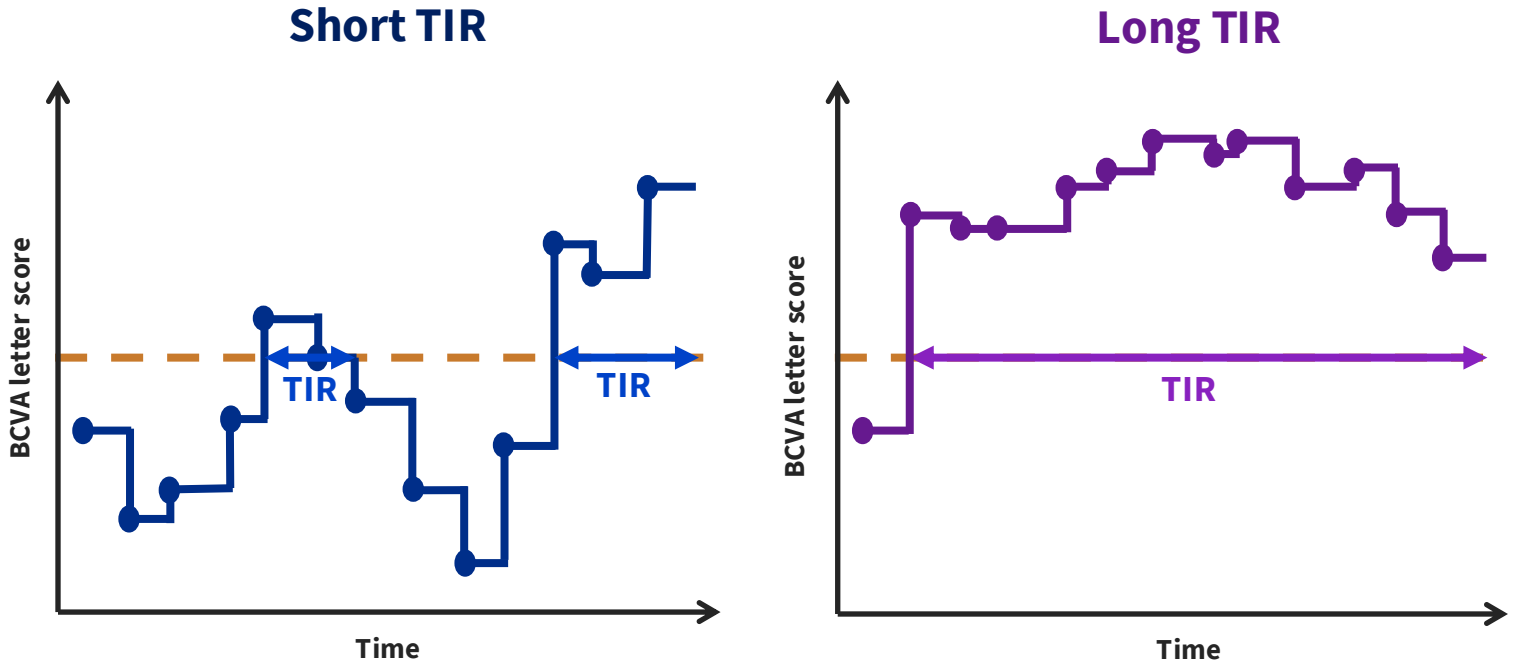
Each row represents treatment experience of one patient. Percent change in treatment burden Month 2 to Month 8 from pre-trial injection burden over same duration; calculation excludes 1 patient in EYP-1901 2 mg arm who discontinued before Month 3 visit. **VEGF,** vascular endothelial growth factor. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Post Hoc Analysis • BCVA Time in Range (TIR)

Measures the Duration of Time Vision is Maintained at or Above a Clinically Relevant Threshold

- Traditional measurements at fixed timepoints **do not capture vision fluctuations** over time[1]
- TIR can quantify **durability of functional vision**[2]
- Thresholds can be tied to **patient-centric**, **real-world benchmarks**



Selected Thresholds for DAVIO 2

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

Figure adapted from Figure 1B in Kozak I, et al. *Eye (Lond).* 2023;37(16):3367-3375 [CC BY 4.0]. **1.** Frizziero L, et al. Eye (Lond). 2026;40(3):310-318. **2.** Kozak I, et al. Eye (Lond). 2023;37(16):3367-3375. **BCVA,** best-corrected visual acuity; **SE**, Snellen equivalent; **TIR,** time in range.
DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Vision Maintenance with a Single EYP-1901 Dose Similar to On-label Aflibercept 2 mg q8W

Mean BCVA TIR Through Week 32 (Month 8): *All Patients*

- 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**

Post hoc analysis. [a] Analysis in days; results converted to weeks for data visualization. **BCVA**, best-corrected visual acuity; **q8W**, every 8 weeks; **TIR**, time in range. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

Subgroup Analysis • Supplement-Free Eyes

Mean BCVA TIR Through Week 32 (Month 8): *Supplement-Free*

In supplement-free patients, BCVA TIR results were similar across arms

Eyes Without Supplemental Treatment

- EYP-1901 2 mg (n=32)
- EYP-1901 3 mg (n=32)
- Aflibercept 2 mg q8W (n=51)

Post hoc analysis. [a] Analysis in days; results converted to weeks for data visualization. **BCVA**, best-corrected visual acuity; **q8W**, every 8 weeks; **TIR**, time in range. DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

EYP-1901 was Well-Tolerated in Phase 1 and 2 Trials

DAVIO 2 Key Safety Findings

- 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

EYP-1901 has been evaluated in over 190 patients in 4 completed phase 1 and 2 trials to date

17 patients received EYP-1901	**DAVIO** **Phase 1 wet AMD** NCT04747197	**51** patients received EYP-1901	**PAVIA** **Phase 2 NPDR** NCT05383209
102 patients received EYP-1901	**DAVIO 2** **Phase 2 wet AMD** NCT05381948	**21** patients received EYP-1901	**VERONA** **Phase 2 DME** NCT06099184

No EYP-1901-related safety concerns

DAVIO 2 safety data through Month 12. **AMD**, age-related macular degeneration; **DME**, Diabetic macular edema; **NPDR**, non-proliferative diabetic retinopathy; **SAE**, serious adverse event.
DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.
Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

DAVIO 2: Stable Vision and Reduced Treatment Burden with EYP-1901 in Patients with Wet AMD

EYP-1901
bioerodible IVT insert designed to provide sustained release of vorolanib for at least 6 months

Therapeutic levels within hours[a]

No free-floating drug particles

No PEG/PLGA

After 6 months following one dose of EYP-1901:

- Mean change in BCVA **statistically noninferior** vs aflibercept 2 mg q8W
- **>90%** of patients had **stable** (BCVA change < 5 letters) or **improved** (BCVA gain ≥ 5 letters) vision with EYP-1901 3 mg
- **≥85%** overall **reduction in treatment burden** vs pre-trial

The dose investigated in phase 3 trials is 2.686 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. **AMD,** age-related macular degeneration; **BCVA,** best-corrected visual acuity; **IVT,** intravitreal; **PEG**, polyethylene glycol; **PLGA**, poly lactic-co-glycolic acid; **q8W,** every 8 weeks. ClinicalTrials.gov identifiers: Phase 2 DAVIO 2 ,NCT05381948; Phase 3 LUGANO, NCT06668064; Phase 3 LUCIA, NCT06683742.

Data on file. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

LUGANO and LUCIA: Pivotal Phase 3 Trials of Repeat-Dose EYP-1901 vs On-Label Aflibercept 2 mg q8W in Wet AMD

LUGANO & LUCIA

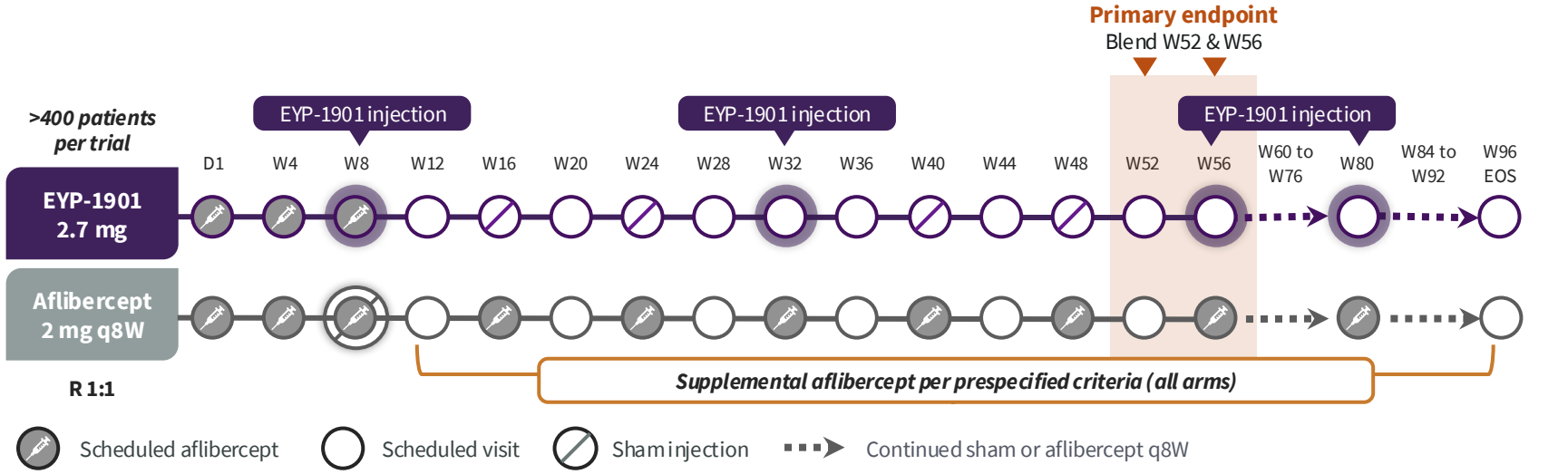
Objective:

Demonstrate EYP-1901 administered every 6 months achieves similar visual outcomes to on-label aflibercept 2 mg q8W while reducing treatment burden

Key Inclusion:

- **Previously-treated** *or* **treatment-naïve** patients with documented diagnosis of wet AMD in the study eye[a]

Topline data expected mid-2026 for LUGANO, with LUCIA to follow



Primary endpoint	Difference in mean change in BCVA from Day 1 to W52 and 56 (averaged) vs aflibercept control
Secondary endpoints	• Safety • Reduction in treatment burden • Percent of eyes supplement-free • Anatomical stability

Primary **efficacy** endpoint at 12 months

Safety monitored for 24 months

*Based on interim review of masked safety data (all treatment arms), the **observed safety profile is consistent** with previous EYP-1901 clinical trials[1]*

The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] Disease onset at any time before Screening. Previously-treated patients must have been treated for wet AMD with ≥2 anti-VEGF IVT injections (i.e., aflibercept 2 mg/8 mg, bevacizumab, ranibizumab, or faricimab) in the previous 6 months per standard-of-care in the study eye before Screening. 1. EyePoint Announces Third Consecutive Positive DSMC Recommendation for Phase 3 Wet AMD Trials for DURAVYU™, Building Confidence Ahead of Mid-2026 Topline Data. Press release. May 14, 2026. Accessed May 14, 2026. https://investors.eyepoint.bio/news-releases/news-release-details/eyepoint-announces-third-consecutive-positive-dsmc. Clinicaltrial.gov identifiers: LUGANO, NCT06668064; LUCIA, NCT06683742.

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