Bioerodible EYP-1901 (vorolanib intravitreal insert) for Diabetic Macular Edema: From the Phase 2 VERONA Trial to Pivotal Phase 3 Program

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Disclaimer

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.

Disclosures

Presenter Disclosures

- Consultant/Advisory: Abbvie, Adverum, Alcon, Bausch & Lomb, EyePoint, 4DMT, Genentech, Iveric Bio, Neurotech, Opthea, Topcon, Zeiss

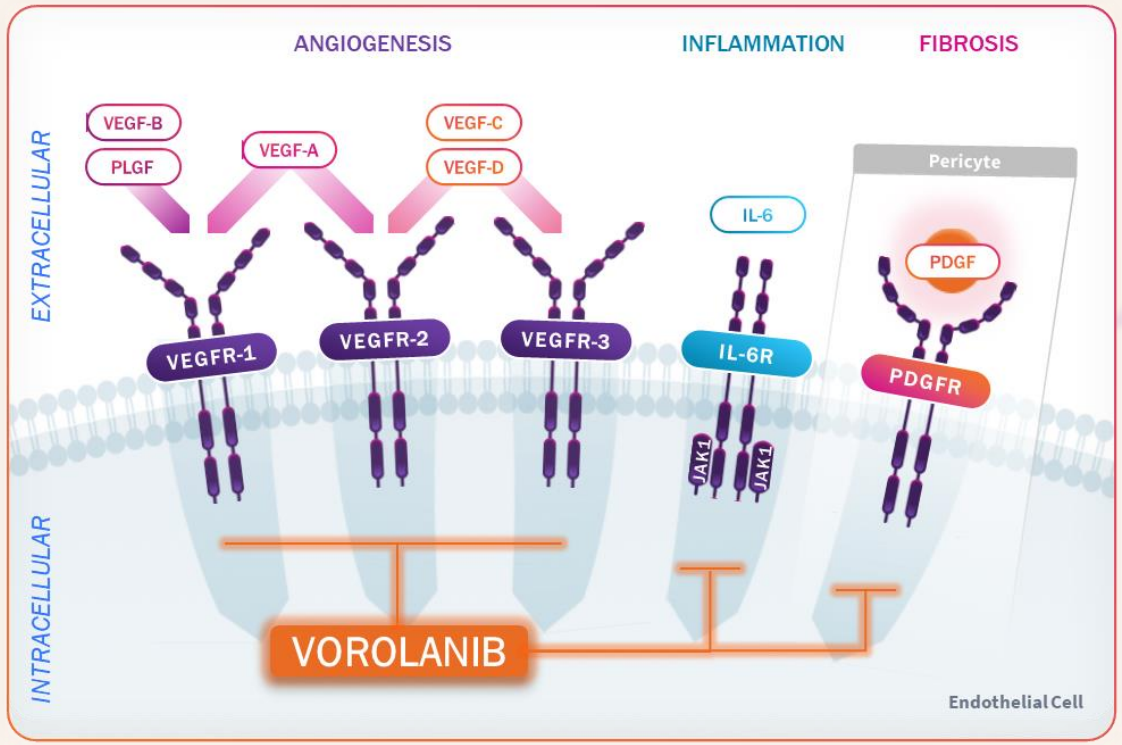
Study Disclosures

- Funding was provided by EyePoint for the study and third-party writing support by Nibedita Gupta, PhD, and Dionne Turnbull, PhD, of Koahana, Inc.

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

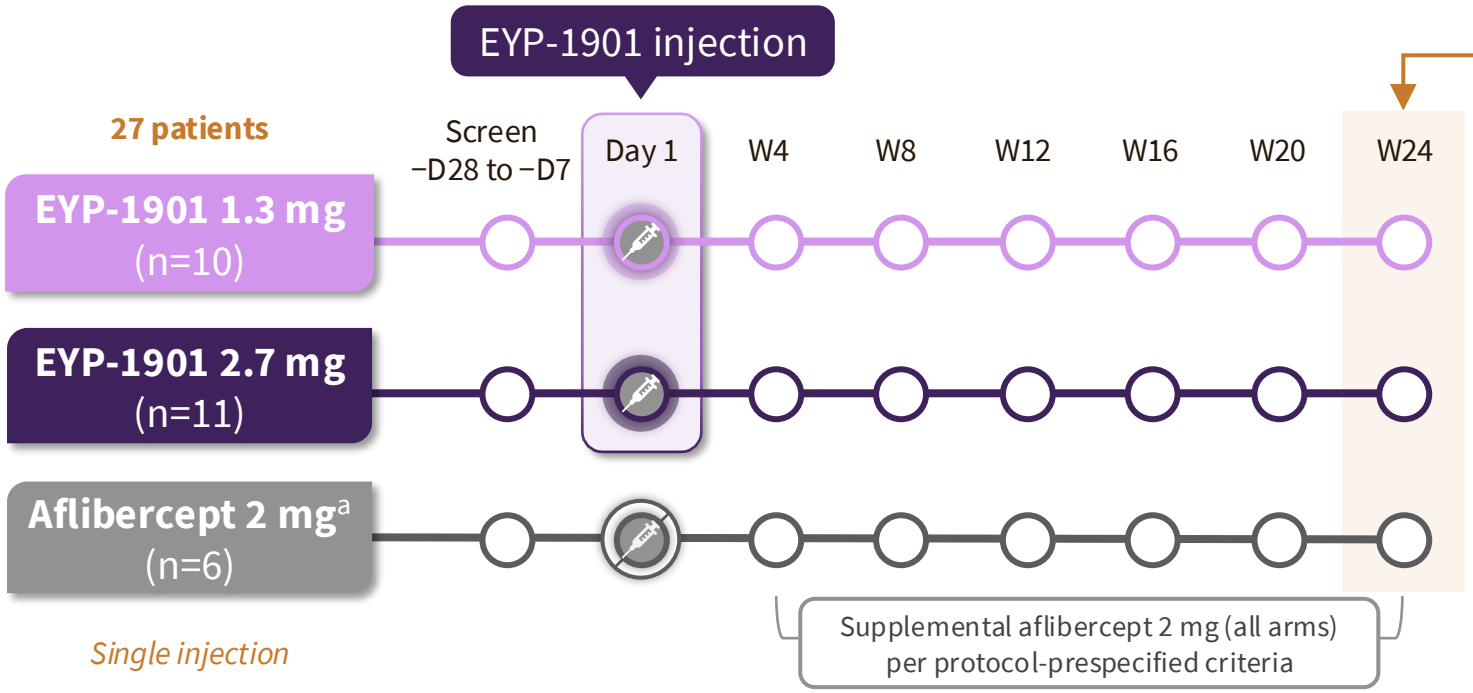
The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] Data from preclinical studies. Following a single injection of EYP-1901 in Dutch-Belted rabbits, vorolanib reached concentrations exceeding IC_{50} in the retina and RPE within 8 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*. Sep-Oct 2024;8(5):577–586.

IC_{50}, half-maximal inhibitory concentration; **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.

VERONA: Phase 2 Trial of EYP-1901 vs Aflibercept in DME



Primary endpoint

Time to first supplemental anti-VEGF injection

Scheduled aflibercept

Scheduled visit

Sham injection

Starting at Week 4

- BCVA reduction 5–9 letters on 2 consecutive visits and CST increase >75 µm[b,c] ***OR***
- BCVA reduction ≥10 letters due to DME[b] ***OR***
- CST increase ≥100 µm[c] vs Baseline ***OR***
- Investigator discretion

Starting at Week 12

- Lack of 10% reduction in CST vs Baseline

VERONA enrolled patients with active DME

- **~2.7 anti-VEGF injections in past year**
  (mean; range 1–8 injections)
- **~3 years since diagnosis**
  (mean; range, <1–10 years)
- **~20/50 Snellen equivalent**
  (mean 66–67 ETDRS letters; range 46–75 letters)
- **~392–430 µm CST**
  (mean; range, 320–645 µm)

[a] After screening, patients received a single aflibercept injection at Day 1 and were evaluated monthly for supplemental treatment (off-label aflibercept use). There was no loading phase. [b] Relative to best on study measurement. [c] CST as measured by SD-OCT.
BCVA, best-corrected visual acuity; **CST**, central subfield thickness; **D**, day; **DME**, diabetic macular edema; **SD-OCT**, spectral-domain optical coherence tomography; **VEGF**, vascular endothelial growth factor; **W**, week. Clinicaltrials.gov identifier: VERONA NCT06099184.

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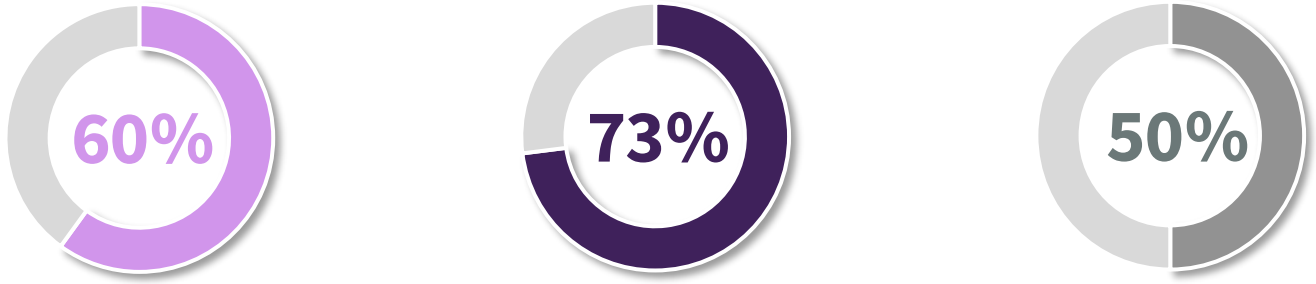
Primary Endpoint Met

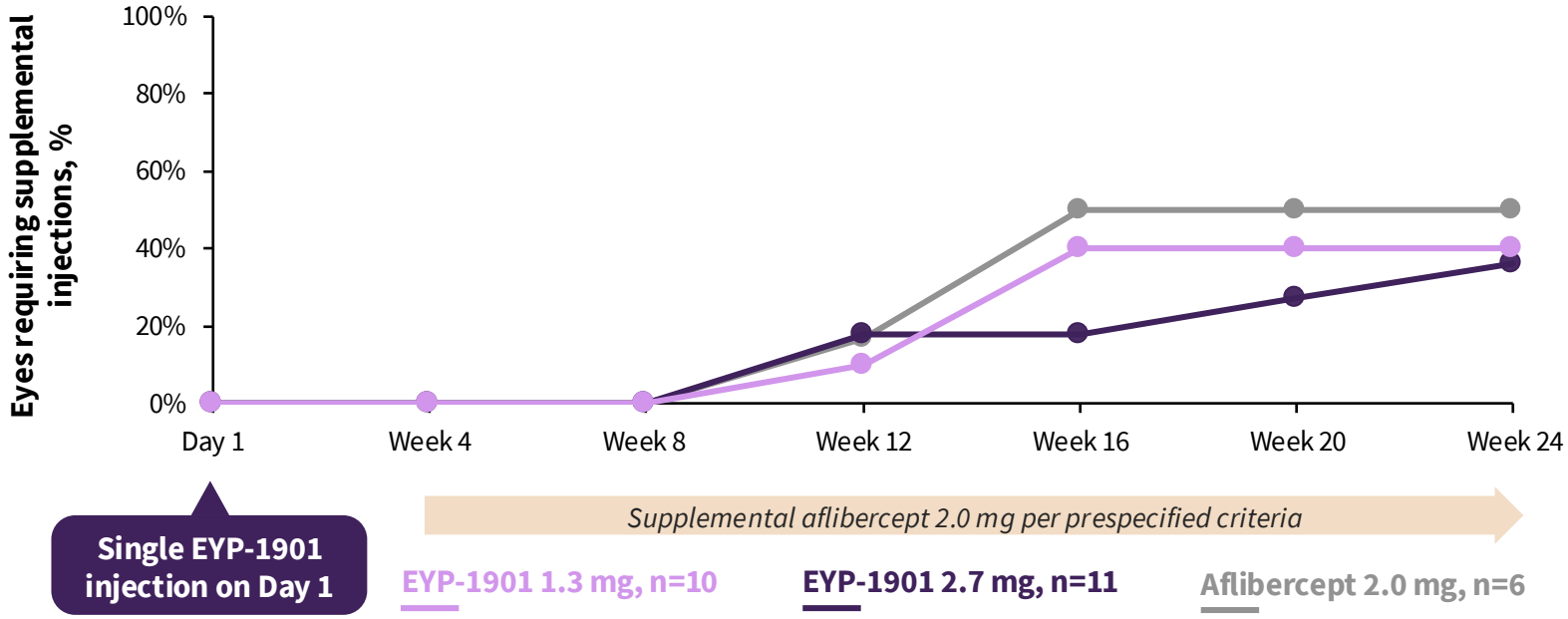
Both EYP-1901 dose levels demonstrated extended time to first supplemental treatment vs aflibercept

- Majority of EYP-1901 patients supplement-free up to Week 24

Cumulative Supplement-Free Rates up to Week 24[a] *(Full Analysis Set)*



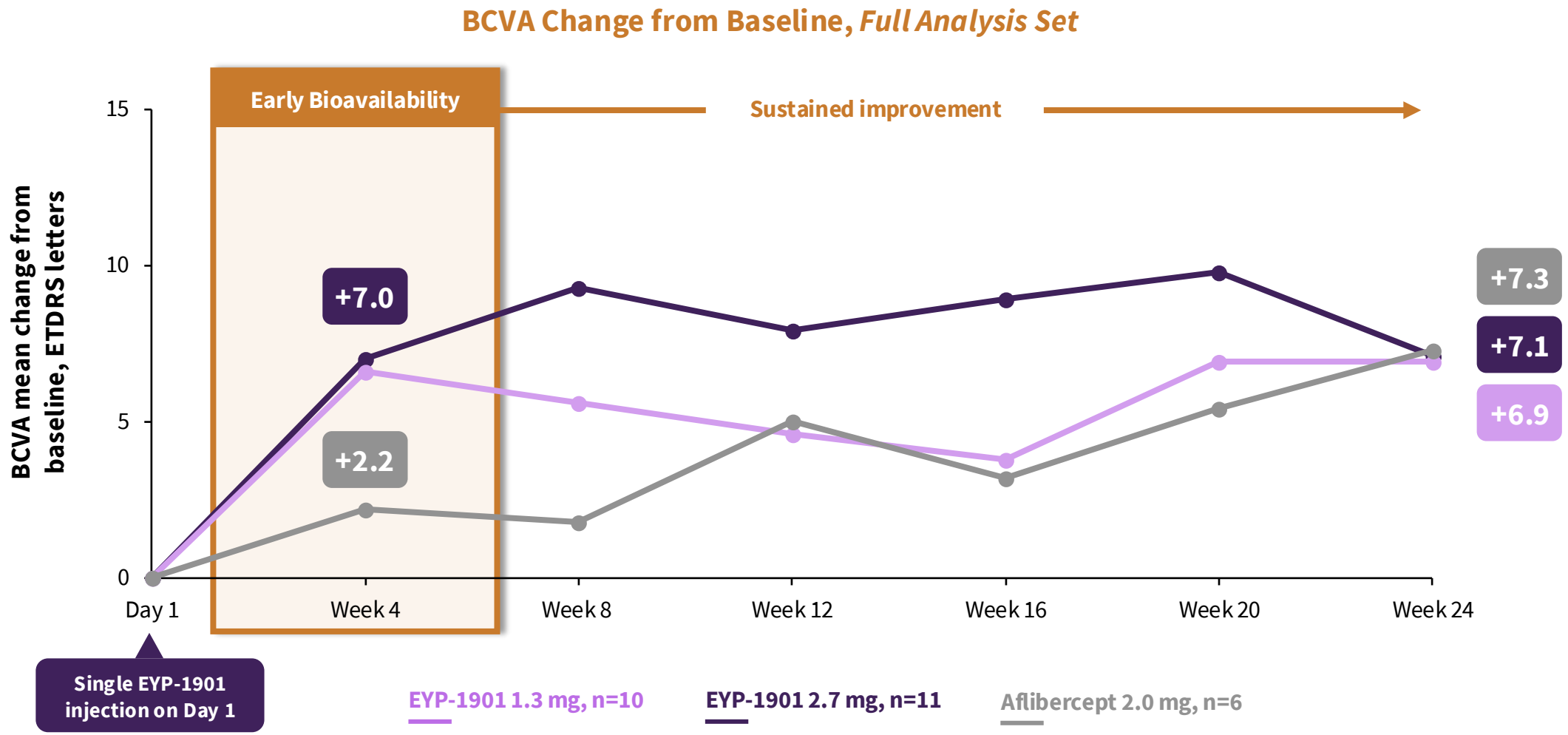
Summary of Eyes Requiring Supplemental Injections *(Full Analysis Set)*



Graph depicts supplemental-injection rates through (i.e., including) the specified study week. [a] Supplement-free rates up to Week 24 reflect rates prior to any treatments given during the Week 24 visit.
Clinicaltrials.gov identifier: VERONA NCT06099184.

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.

BCVA: Early and Sustained Vision Gains with a Single EYP-1901 Dose



BCVA, best-corrected visual acuity; **ETDRS,** Early Treatment Diabetic Retinopathy Study. Clinicaltrials.gov identifier: VERONA NCT06099184.

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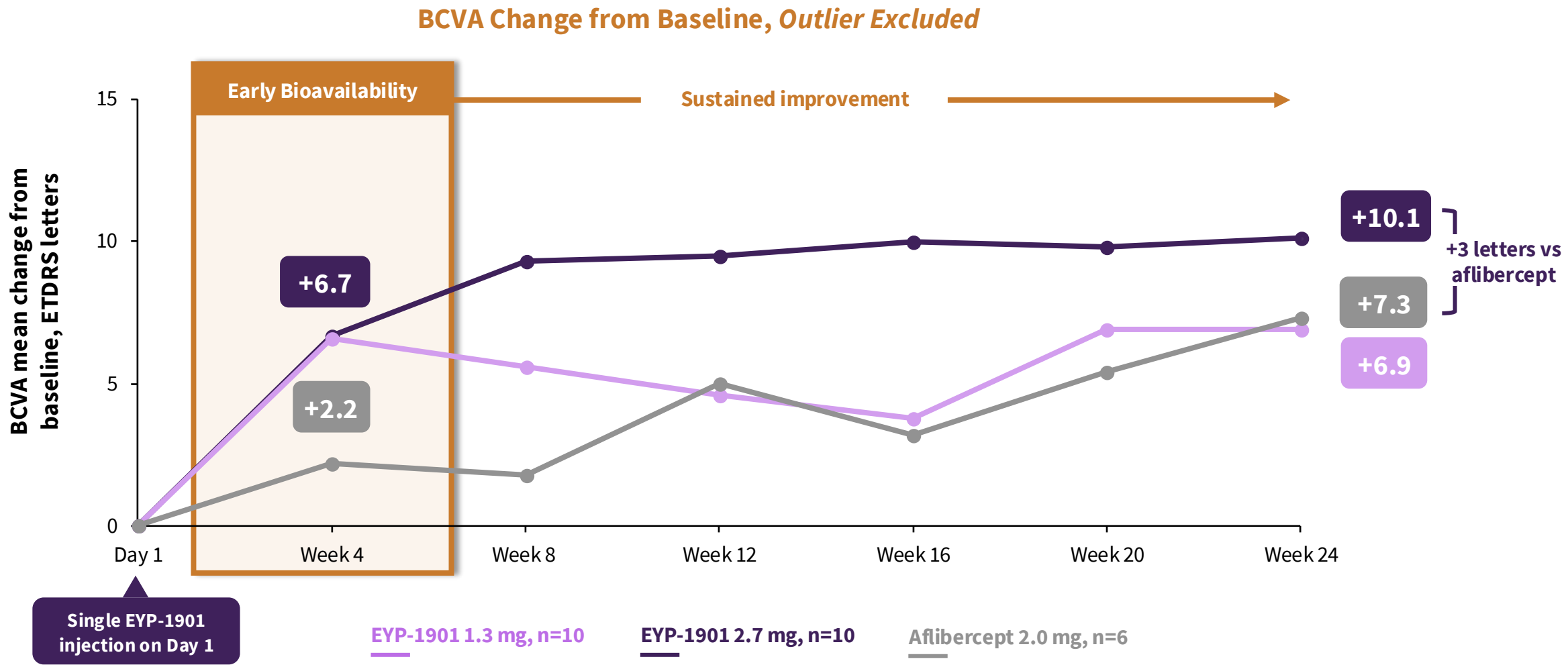
BCVA: Early and Sustained Vision Gains with a Single EYP-1901 Dose

+10 letter vision gain in EYP-1901 2.7 mg arm after excluding single outlier



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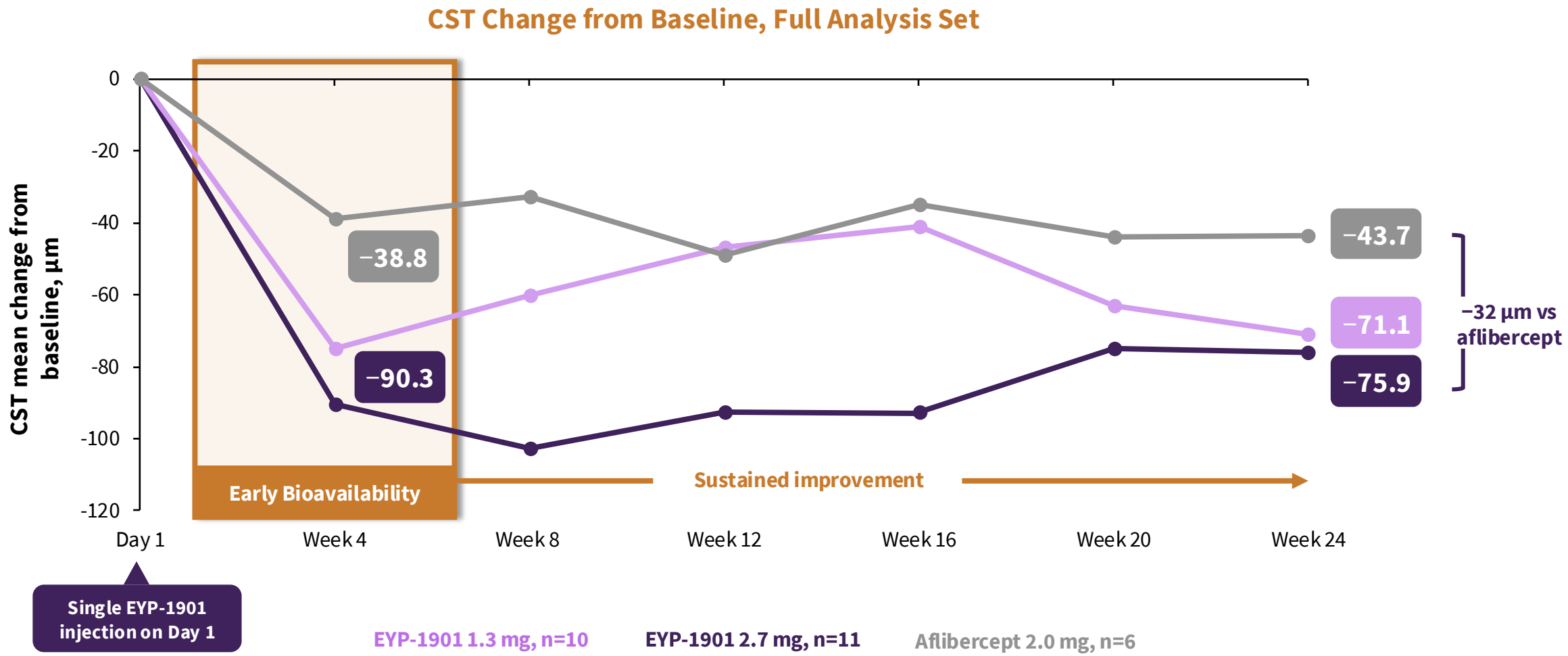
CST: Early and Sustained Anatomic Improvement with a Single EYP-1901 Dose



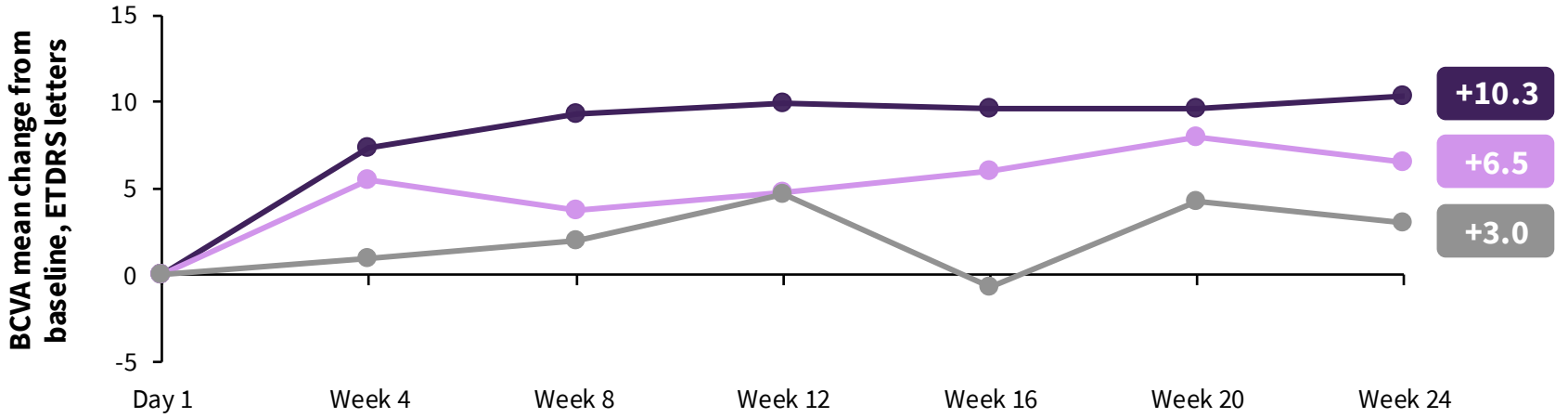
CST, central subfield thickness. Clinicaltrials.gov identifier: VERONA NCT06099184.

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.

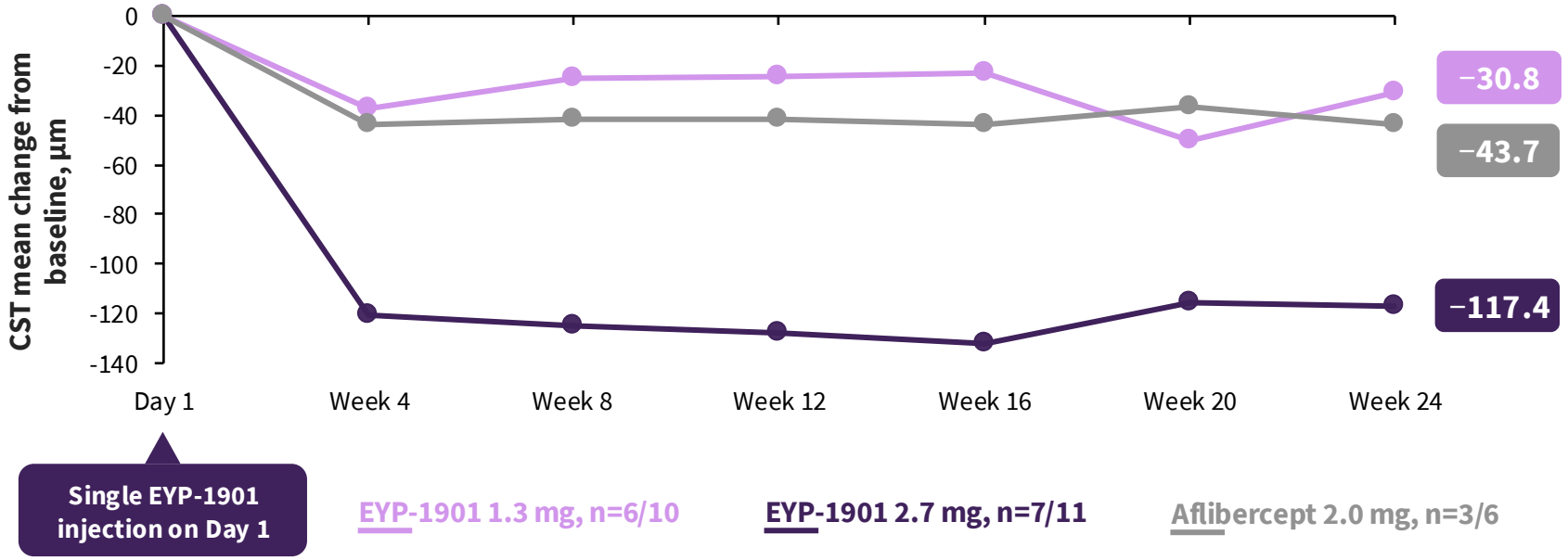
Subgroup Analysis

Single EYP-1901 treatment demonstrated improved vision and anatomic outcomes

BCVA Change from Baseline, *Supplement-free Subgroup*



CST Change from Baseline, *Supplement-free Subgroup*



Supplement-free is defined as patients who did not receive a supplemental treatment at any point during the study.

BCVA, best-corrected visual acuity; **CST**, central subfield thickness; **ETDRS**, Early Treatment Diabetic Retinopathy Study. Clinicaltrials.gov identifier: VERONA NCT06099184.

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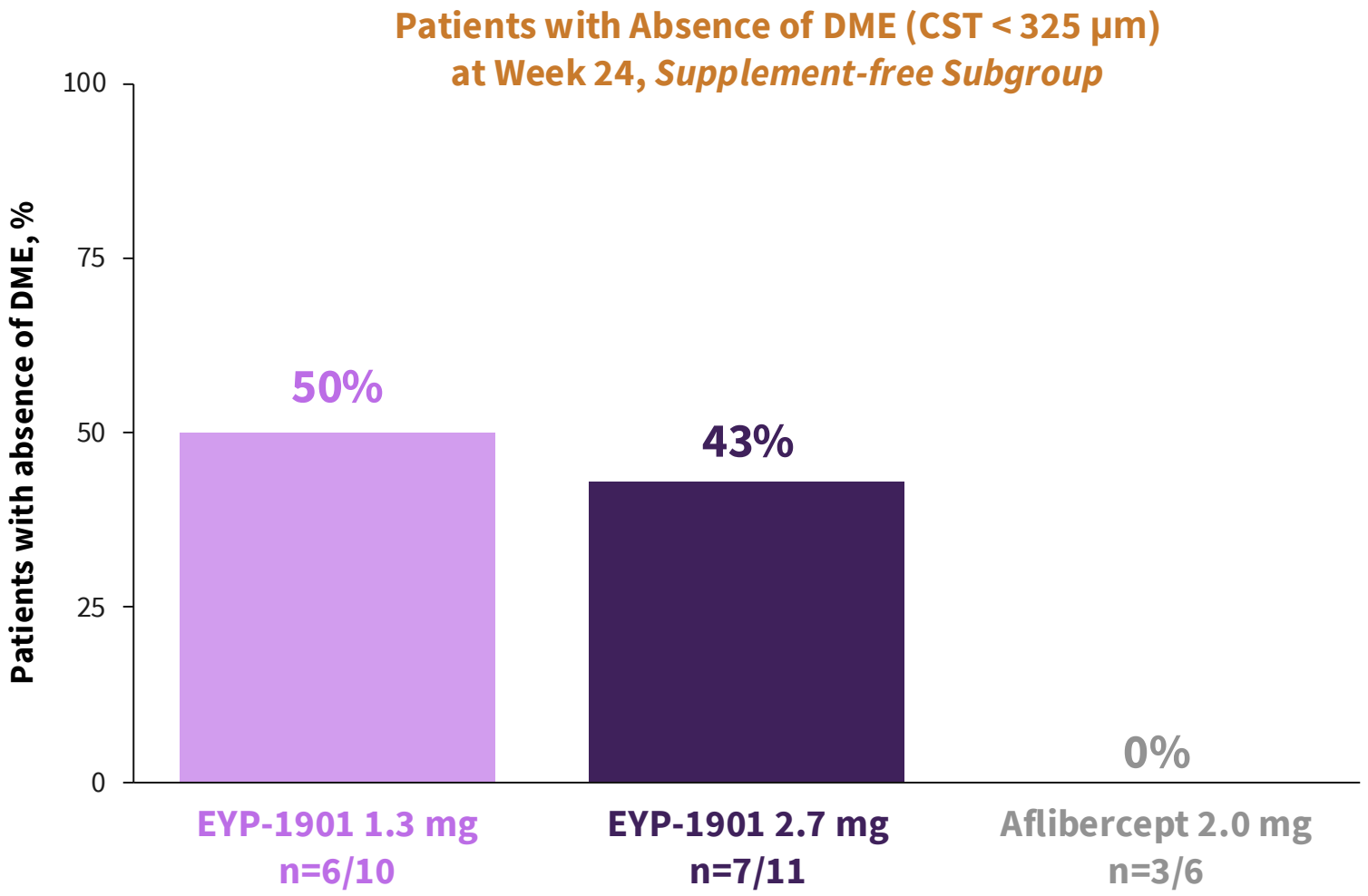
Subgroup Analysis

Disease control in supplement-free eyes with single EYP-1901 dose



Supplement-free is defined as patients who did not receive a supplemental treatment at any point during the study.
CST, central subfield thickness; **DME,** diabetic macular edema. Clinicaltrials.gov identifier: VERONA NCT06099184.
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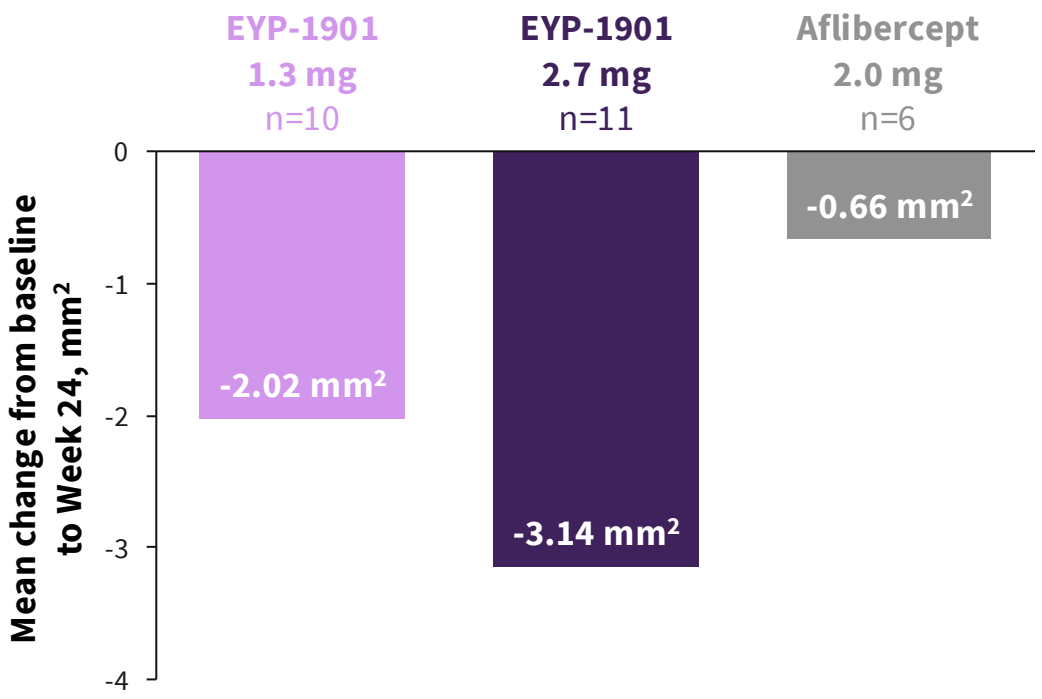
Macular Leakage: Dose-Dependent Reduction Observed with a Single EYP-1901 Dose

Macular leakage is a biomarker of vascular stability in DME[1]

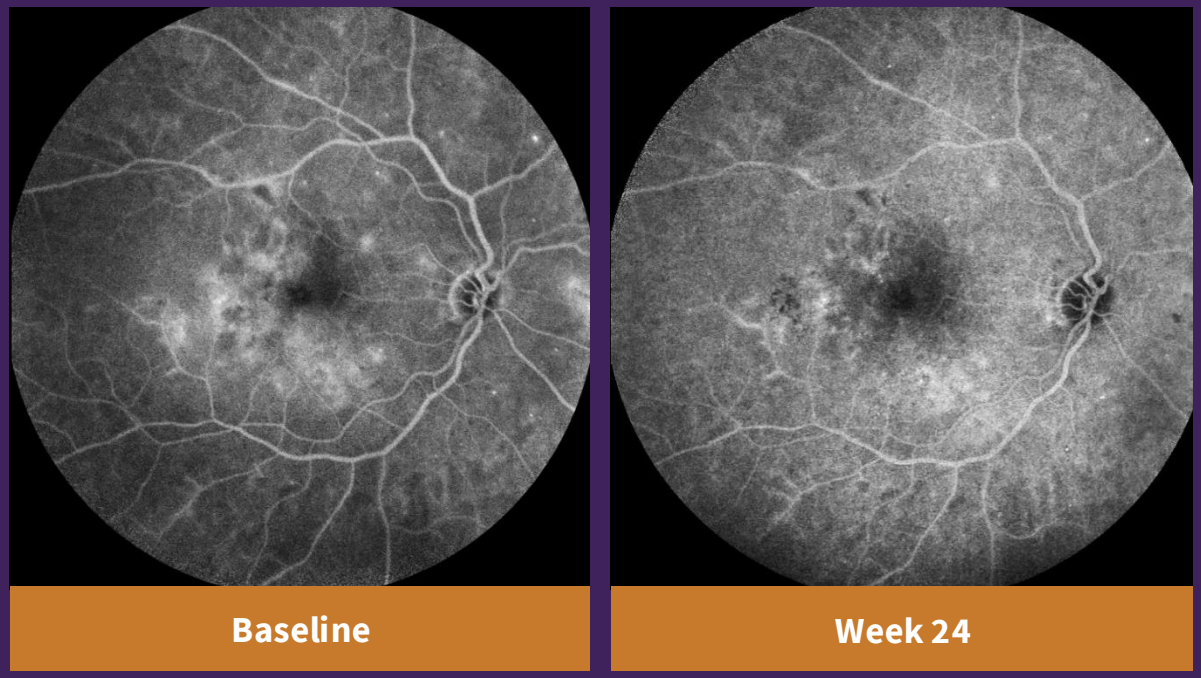
Vascular Leakage Area Change from Baseline to Week 24[a]



Illustrative patient case:
not representative of all observed cases or predicative of treatment outcomes

Case: EYP-1901 2.7 mg

Single EYP-1901 2.7 mg dose with no supplementation



Marked reduction in leakage area at Week 24

Full analysis set. [a] Change from baseline in vascular leakage (mm²) in the macula and in the total retinal area. **1.** Goldberg RA, et al. *Opthalmol Retina*. 2025 Jun;9(6):515-526. **DME,** diabetic macular edema. Clinicaltrials.gov identifier: VERONA NCT06099184.

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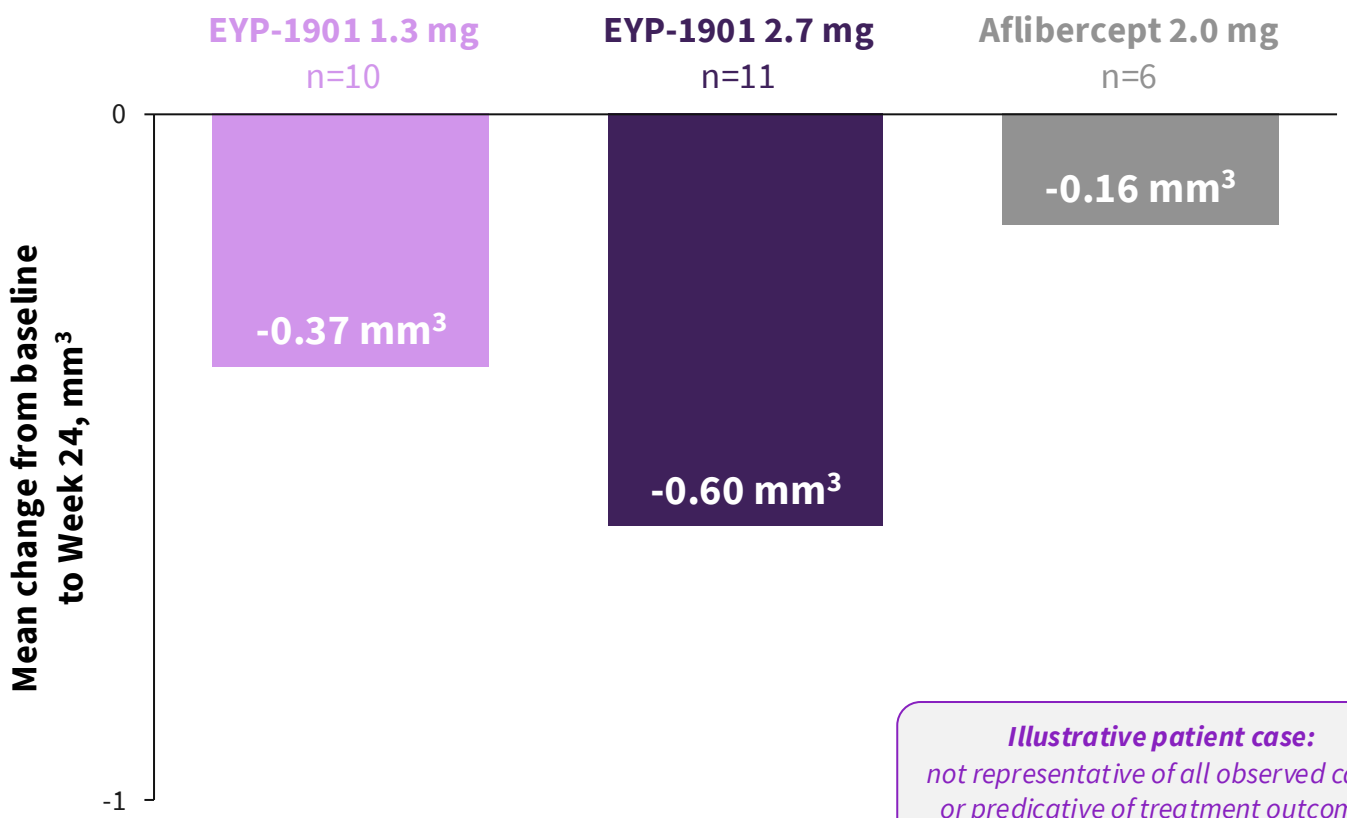
Macular Volume: Dose-Dependent Reduction Observed with a Single EYP-1901 Dose

Total Macular Volume Change from Baseline to Week 24



Illustrative patient case:
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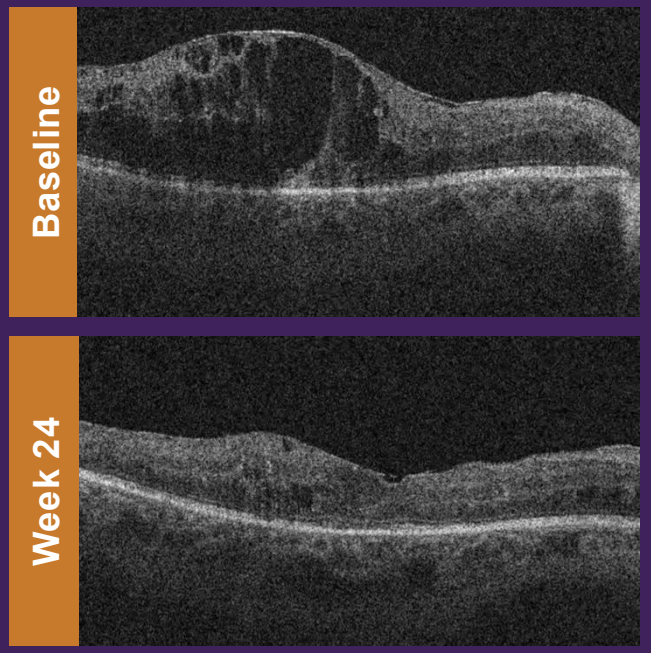
Case: EYP-1901 2.7 mg



Marked reduction in macular volume at Week 24 with a single dose of EYP-1901

Clinicaltrials.gov identifier: VERONA NCT06099184.

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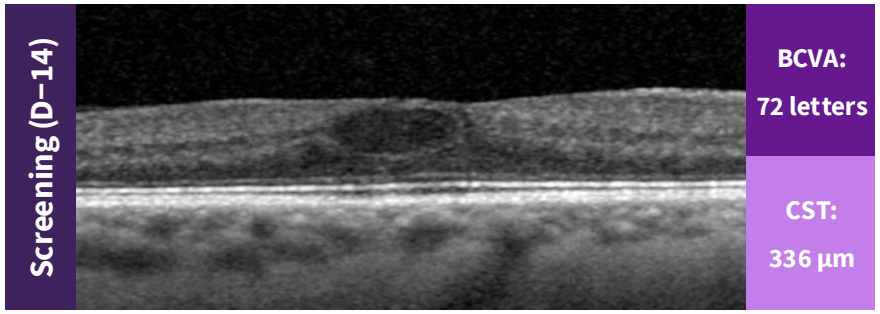
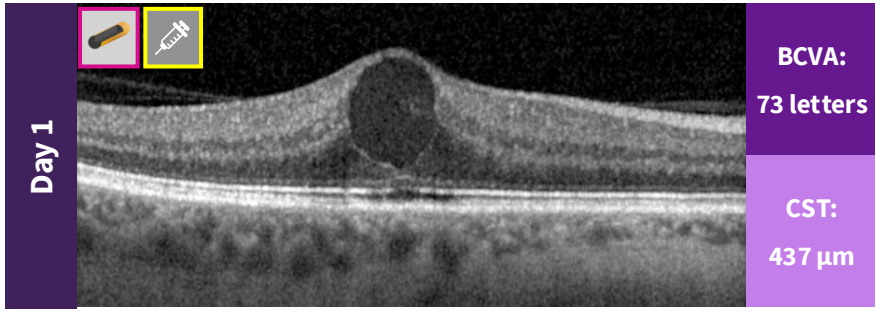
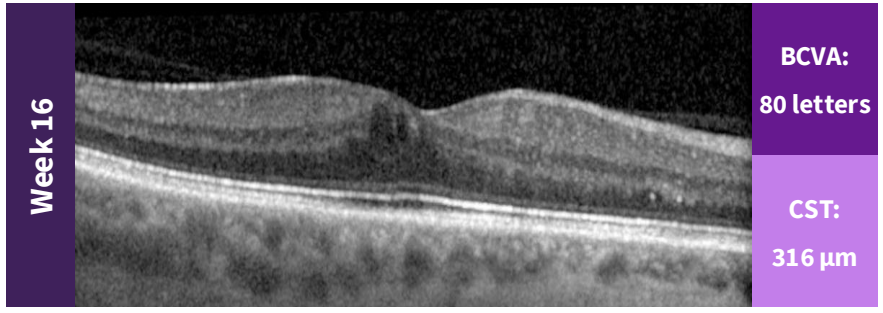
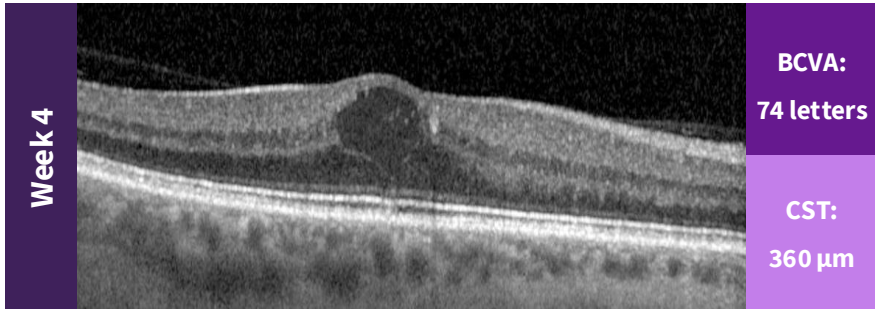
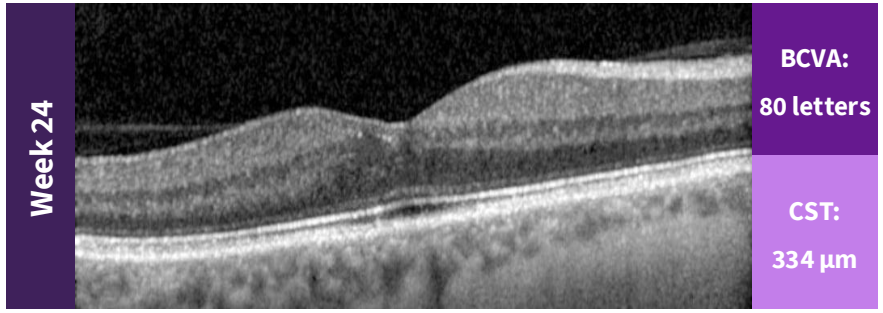
Selected Case Study: Continued Drying at Week 24 with Improved VA After a Single EYP-1901 2.7 mg Dose and No Supplementation

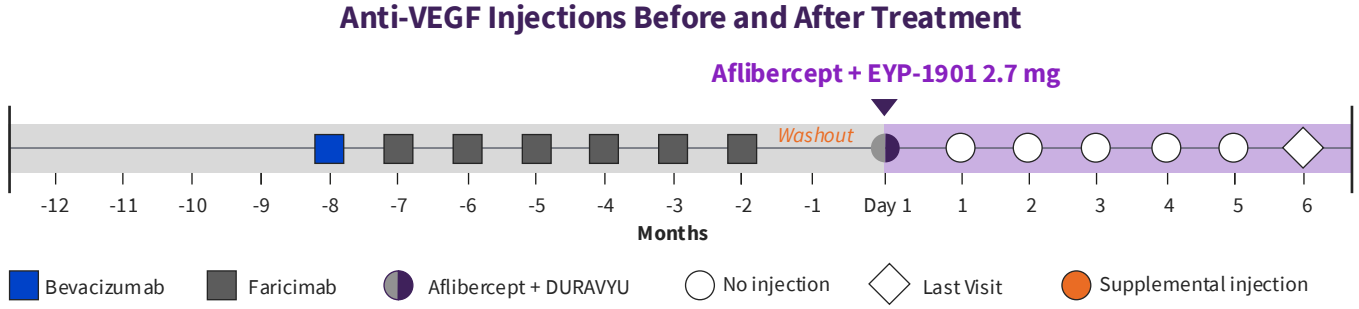












Patient presented with fluid at Screening and Day 1

Fluid dried after a single dose of EYP-1901

Vision improved by +8 letters

EYP-1901 | Scheduled aflibercept | Supplemental aflibercept

Illustrative patient case:
not representative of all observed cases or predicative of treatment outcomes

BCVA, best-corrected visual acuity; **CST**, central subfield thickness; **D**, day; **VA**, visual acuity; **VEGF**, vascular endothelial growth factor. Clinicaltrials.gov Identifier: VERONA NCT06099184.

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 Well-Tolerated in Phase 1 and Phase 2 Trials

VERONA Key Safety Findings

- No EYP-1901–related ocular or systemic SAEs
- No cases of:
  - Endophthalmitis
  - Retinal vasculitis (occlusive or non-occlusive)
  - Intraocular inflammation (IOI)
  - Insert migration into the anterior chamber
- No discontinuations

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

AMD, age-related macular degeneration; **DME**, diabetic macular edema; **IOI**, intraocular inflammation; **NPDR**, non-proliferative diabetic retinopathy; **SAE**, serious adverse event.
Clinicaltrials.gov Identifier: VERONA NCT06099184.
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.

VERONA Met its Primary Endpoint

Sustained disease control ● Fewer injections ● Favorable safety profile

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

With one dose of EYP-1901:

- **Extended time to first supplemental treatment** vs aflibercept 2.0 mg
  - >**70%** of eyes treated with EYP-1901 2.7 mg **supplement-free** up to Week 24
- **Early and sustained improvement** in vision and anatomic outcomes without a full load of aflibercept
- **Reductions** in **macular leakage area** and total **macular volume**
- EYP-1901 was **well-tolerated**, with no related ocular or systemic SAEs

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.[1]

1. Lynch J, et al. Presentation at ARVO: May 3–7 2026; Denver, CO. **IVT,** intravitreal; **PEG**, polyethylene glycol; **PLGA**, poly lactic-co-glycolic acid; **RPE**, retinal pigment epithelium; **SAE**, serious adverse event. Clinicaltrials.gov Identifier: VERONA NCT06099184.

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Pivotal Phase 3 Trials of Repeat-Dose EYP-1901 vs On-Label Aflibercept 2 mg q8W in DME

COMO & CAPRI

Objective:

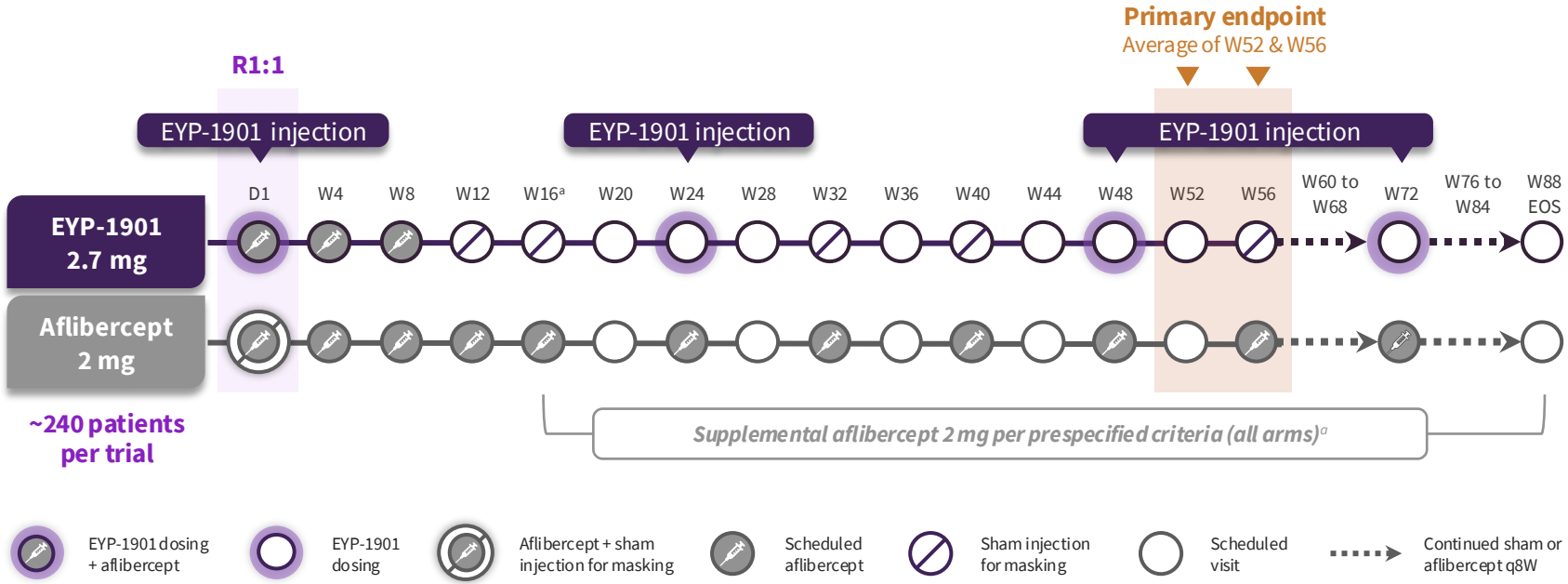
Demonstrate that EYP-1901 administered every six months achieves similar visual outcomes to on-label aflibercept 2 mg while reducing treatment burden

Key Inclusion

Treatment-naïve *or* **previously-treated** patients with documented diagnosis of DME in the study eye

Currently enrolling

*First patients dosed **Q1 2026**, topline data anticipated **2H 2027***



Primary endpoint	Difference in mean change in BCVA from Day 1 to Week 52 and 56 (blended) versus aflibercept control
Secondary endpoints	• Safety • Reduction in treatment burden • Percent of eyes supplement-free • Anatomical stability

Primary **efficacy** endpoint at Week 52/56

Safety monitored for 88 weeks

The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] Criteria for supplemental injection assessed starting after Week 16 and at every subsequent visit.
BCVA, best-corrected visual acuity; **D**, day; **DME**, diabetic macular edema; **EOS**, end of study; **q8W**, every 8 weeks; **R**, randomization; **W**, week. Clinicaltrials.gov identifiers: COMO NCT07449936; CAPRI NCT07449923.

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.