# Update on EYP-1901 Clinical Trials in nAMD and DME

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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: ANI Pharmaceuticals, Alcon, Bausch, EyePoint, Outlook Therapeutics, RecensMedical, Inc
- Speakers Bureau: Apellis, Biogen, Coherus, Genentech, Iveric Bio, Regeneron
- Grant Support: Allergan/Abbvie, EyePoint

## Study Disclosures


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

# Key Takeaways

## Designed for durable disease control

EYP-1901 provides sustained release of vorolanib via a bioerodible intravitreal insert

## Vorolanib has a multi-MOA for retinal disease

Vorolanib is a TKI that inhibits all VEGF receptors, PDGF receptor, and blocks inflammatory IL-6 signaling

## EYP-1901 has the potential to improve long-term visual outcomes in nAMD and DME

Informed by positive phase 2 trials; phase 3 trials are ongoing

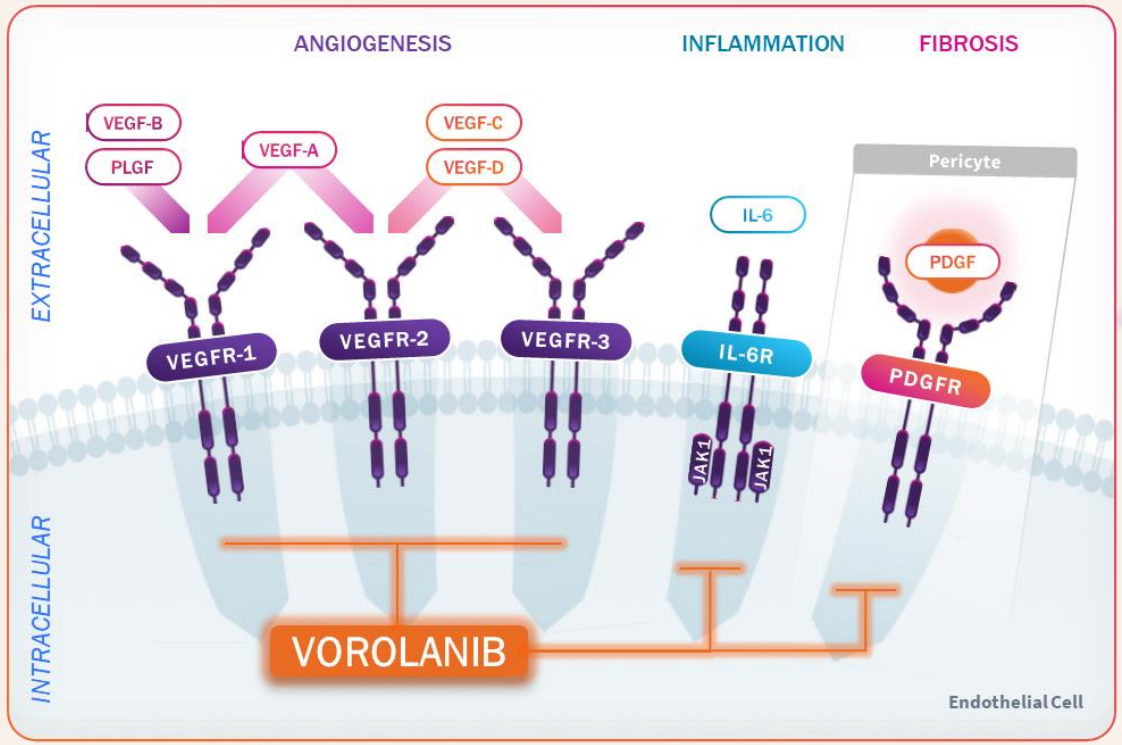
**DME,** diabetic macular edema; **IL-6,** interleukin-6; **MOA,** mechanism of action; **nAMD,** neovascular age-related macular degeneration; **PDGF,** platelet-derived growth factor; **TKI,** tyrosine kinase inhibitor; **VEGF,** vascular endothelial growth factor.

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 (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

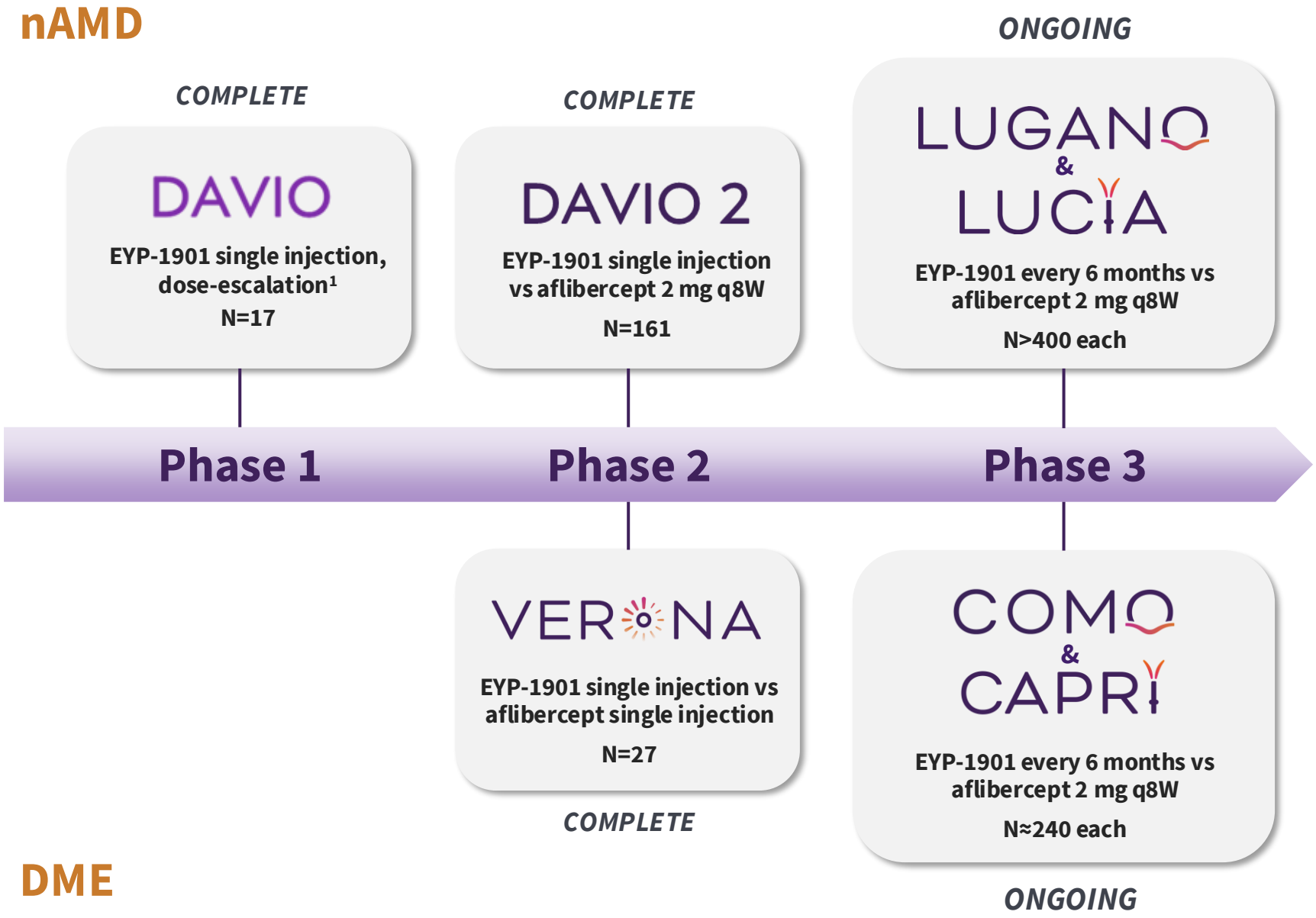
The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] Data from preclinical studies. Following a single injection of EYP-1901 in Dutch-Belted rabbits, vorolanib reached concentrations exceeding $IC_{50}$ in the retina and RPE within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

# Clinical Trials for EYP-1901 in nAMD and DME

**EYP-1901 is designed to provide disease control comparable with current, on-label SoC with fewer injections**




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. **DME**, diabetic macular edema; **nAMD,** neovascular age-related macular degeneration; **q8W**, every 8 weeks; **SoC**, standard of care. Clinicaltrial.gov identifiers: COMO, NCT07449936; CAPRI, NCT07449923. DAVIO, NCT04747197; DAVIO 2, NCT05381948; LUGANO, NCT06668064; LUCIA, NCT06683742; VERONA, NCT06099184.

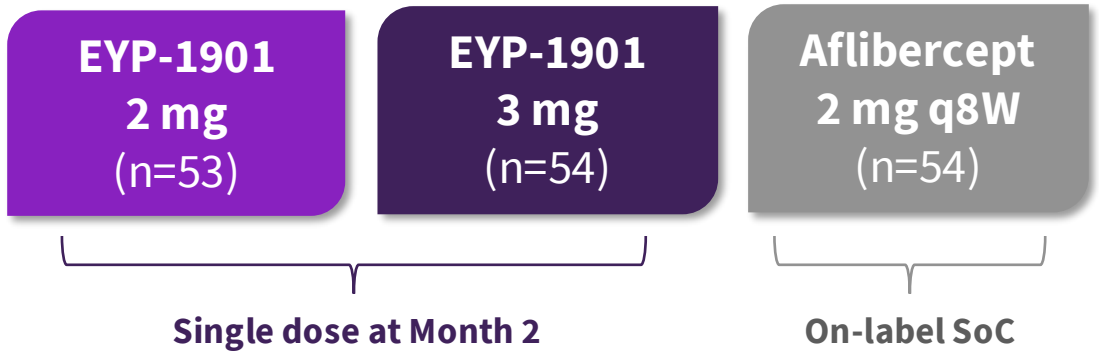
Data on file. These data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

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

## Study Design

**161 patients with previously-treated nAMD**

*Trial duration 56 weeks*




**Primary endpoint: Mean BCVA change at Month 7/8**

*Noninferiority margin −4.5 letters*

## Primary endpoint met

**Mean BCVA change with EYP-1901 statistically noninferior to aflibercept 2 mg q8W**

- >85% of EYP-1901-treated patients had **stable (BCVA change <5 letters) or improved (BCVA gain ≥5 letters) vision** with a single dose
- **Strong and stable anatomical control** with EYP-1901; no sawtooth pattern
- **Reduced treatment burden** with ≥85% overall reduction with a single dose of EYP-1901 vs pre-trial
- **Favorable safety profile observed**; no EYP-1901-related safety concerns

Chakravarthy U. "EYP 1901 in nAMD: Updated DAVIO 2 Results." Presented at FLORetina ICOOR 12th International Congress on OCT and OCT Angiography; December 4–7, 2025; Florence, Italy.
**BCVA**, best-corrected visual acuity; **nAMD,** neovascular age-related macular degeneration; **SoC,** standard of care; **q8W**, every 8 weeks.
DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948.

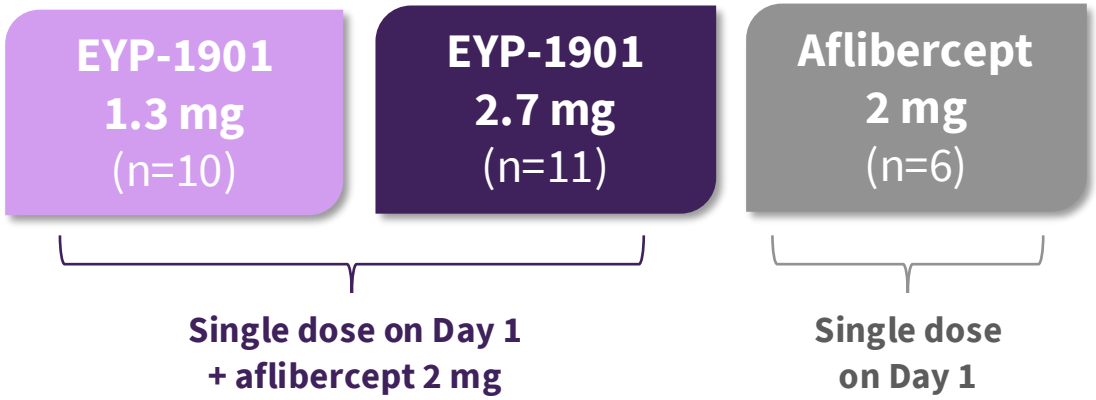
Data on file. These data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled phase 3 clinical trials.

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

## Study Design

**27 patients with active DME**

*Trial duration 24 weeks*




**Primary endpoint:**
**Time to first supplemental anti-VEGF injection**

## Primary endpoint met

**Extended time to first supplemental treatment with EYP-1901 vs aflibercept**

- Clinically **meaningful improvements in BCVA and CST** starting at Week 4 and sustained through Week 24
- **Fewer injections received:** 73% of EYP-1901 2.7 mg treated eyes supplement-free through Week 24 vs 50% with aflibercept 2 mg
- **Favorable safety profile observed**; no EYP-1901-related safety concerns

After screening, all 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.
Grewal DS and Ribeiro R. "VERONA Phase 2 Clinical Trial: Visual, Anatomic, and Angiographic Outcomes with Bioerodible EYP-1901 (vorolanib intravitreal insert) Versus Aflibercept for Diabetic Macular Edema." Presented at 49th Macula Society Annual Meeting; February 25–28, 2026; San Diego, CA.
**BCVA**, best-corrected visual acuity; **CST**, central subfield thickness; **DME**, diabetic macular edema; **VEGF**, vascular endothelial growth factor receptor.
VERONA Clinicaltrials.gov Identifier: 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 2 Trials

## Key Safety Findings in Phase 2 Trials

- No EYP-1901–related ocular or systemic SAEs
- No insert migration into the anterior chamber
- No cases of retinal occlusive vasculitis
- No cases of anterior chamber opacity
- 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[1]** **Phase 1 nAMD** NCT04747197 | **51** patients received EYP-1901 | **PAVIA[3]** **Phase 2 NPDR** NCT05383209 |
| **102** patients received EYP-1901 | **DAVIO 2[2]** **Phase 2 nAMD** NCT05381948 | **21** patients received EYP-1901 | **VERONA[4]** **Phase 2 DME** NCT06099184 |

**No EYP-1901-related safety concerns**

1. Patel S, et al. *Ophthalmol Sci.* Sep-Oct 2024;4(5):100527. 2. Chakravarthy U. "EYP-1901 in nAMD: Updated DAVIO 2 Results." Presented at FLORetina ICOOR 12th International Congress on OCT and OCT Angiography; December 4–7, 2025; Florence, Italy. 3. Almeida DRP and Ribeiro R. PO4762: "PAVIA phase 2 trial of EYP-1901 in nonproliferative diabetic retinopathy: 12-month results." Poster presentation at: Association for Research in Vision & Ophthalmology Annual Meeting; May 4–8, 2025; Salt Lake City, UT. 4. Grewal DS and Ribeiro R. "VERONA Phase 2 Clinical Trial: Visual, Anatomic, and Angiographic Outcomes with Bioerodible EYP-1901 (vorolanib intravitreal insert) Versus Aflibercept for Diabetic Macular Edema." Presented at 49th Macula Society Annual Meeting; February 25–28, 2026; San Diego, CA.

**DME**, Diabetic macular edema; **nAMD,** neovascular age-related macular degeneration; **NPDR**, non-proliferative diabetic retinopathy; **SAE**, serious adverse event.

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.

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

LUGANO & LUCIA

**Objective:**

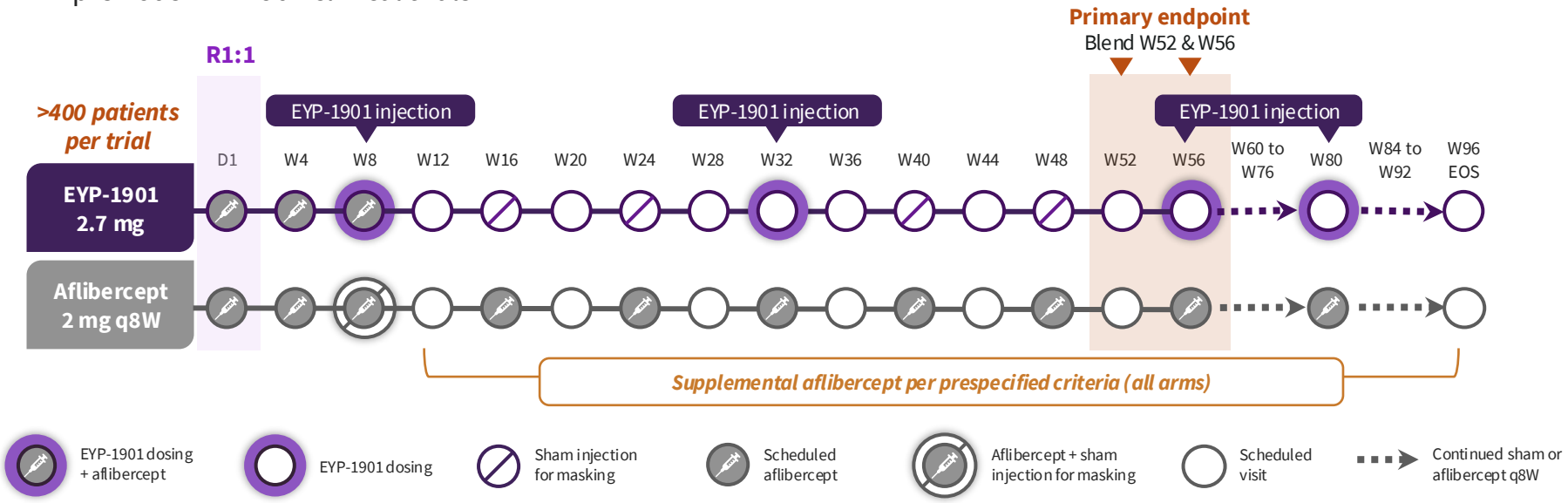
Demonstrate EYP-1901 administered every 6 months achieves similar visual outcomes to on-label aflibercept 2 mg q8W while reducing treatment burden

**Key Inclusion:**

- **Previously-treated** *or* **treatment-naïve** patients with nAMD[a]

**LUGANO Topline Data Expected in Mid-2026; LUCIA to Follow**

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

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

Primary **efficacy** endpoint at 12 months

**Safety** monitored for 24 months

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 nAMD 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. **BCVA,** best-corrected visual acuity; **D,** day; **EOS,** end of study; **IVT,** intravitreal; **nAMD,** neovascular age-related macular degeneration; **q8W,** every 8 weeks; **R,** randomization; **W,** week. Clinicaltrial.gov identifiers: LUGANO, NCT06668064; 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.

# COMO and CAPRI: Phase 3 Trials of Repeat-Dose EYP-1901 vs On-Label Aflibercept 2 mg q8W in DME

COMO & CAPRI

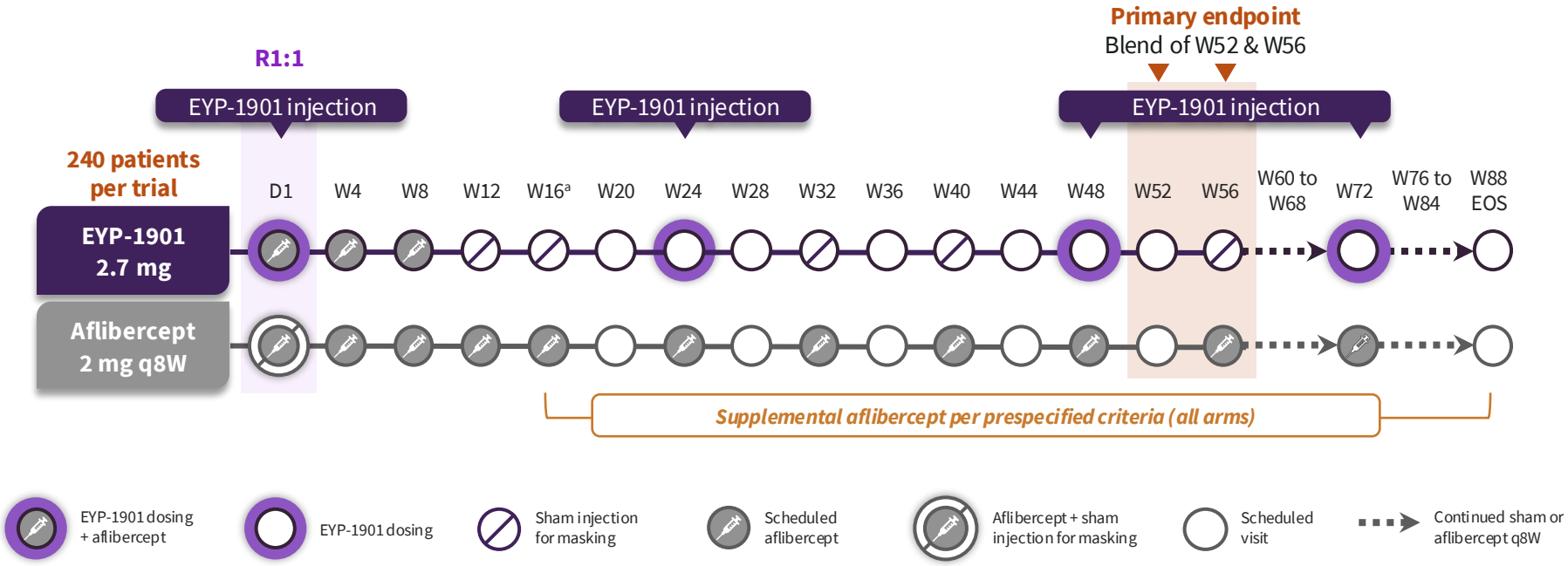
**Objective:**

Demonstrate that EYP-1901, when 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 DME

**Enrollment Completion Expected Q3 2026 with Topline Data Anticipated Q4 2027**




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

Primary **efficacy** endpoint at 12 months

**Safety** monitored for 22 months

The dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. **BCVA,** best-corrected visual acuity; **D**, day **DME**;, diabetic macular edema; **EOS**, end of study; **q8W**, every 8 weeks; **R**, randomization; **W**, week.
Clinicaltrial.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.

# A Robust Clinical Trial Program Supports the Potential of EYP-1901 to Provide Durable Treatment in nAMD and DME

## 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**

- **DAVIO 2** demonstrated **stable vision, anatomical control, and reduced treatment burden**
- **VERONA** demonstrated **early and sustained improvement** in vision and anatomic outcomes
- In both trials, EYP-1901 was **well-tolerated**, with no EYP-1901-related safety concerns

**Phase 3 LUGANO topline data expected in mid-2026; LUCIA to follow**

**Enrollment completion for COMO and CAPRI expected Q3 2026; topline data anticipated Q4 2027**

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. **DME,** diabetic macular edema; **IVT,** intravitreal; **nAMD,** neovascular age-related macular degeneration; **PEG,** polyethylene glycol; **PLGA,** poly lactic-co-glycolic acid; **SAE**, serious adverse event.
Clinicaltrial.gov identifiers: COMO, NCT07449936; CAPRI, NCT07449923. DAVIO 2, NCT05381948; LUGANO, NCT06668064; LUCIA, NCT06683742; 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.