DAVIO 2: A Phase 2 Trial of EYP-1901 (vorolanib intravitreal insert) versus Aflibercept for Previously-Treated Neovascular Age-Related Macular Degeneration

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On behalf of the DAVIO 2 Investigator Group

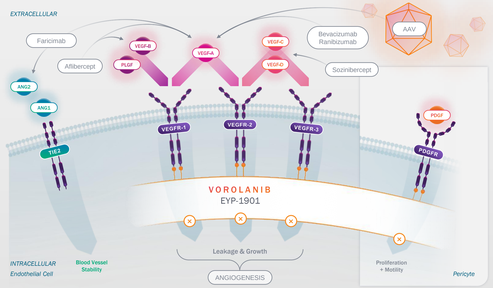
EYP-1901 (DURAVYU™)

Consistent, controlled, and sustained release of vorolanib for at least 6 months via a bioerodible intravitreal insert

In development for the treatment of retinal exudative diseases

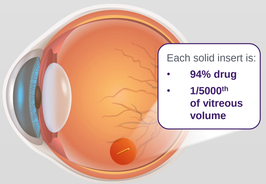
Vorolanib

Potent and selective receptor tyrosine kinase inhibitor working intracellularly to provide pan-VEGFR inhibition



EYP-1901

Sustained release of vorolanib using bioerodible, intravitreal drug delivery technology (Durasert E™)



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

Practical design
Administered via standard, in-office intravitreal injection with no cold storage required

Immediate
Vorolanib is immediately bioavailable, reaching target tissues within hours after administration with no delay

Consistent
Vorolanib is delivered as a continuous dose with zero-order kinetics and no fluctuations

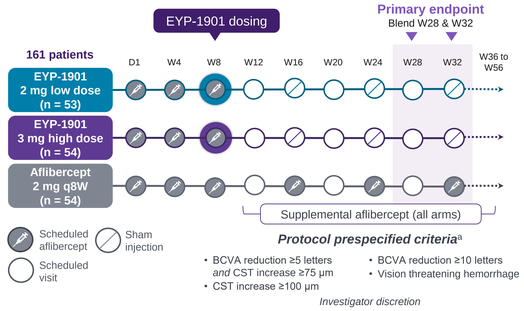
Sustained
Provides sustained VEGF receptor inhibition through at least 6 months

Controlled
Ensures controlled drug release and no free-floating drug particles by fully eluting vorolanib before matrix bioerosion

Durasert E not drawn to scale, for illustrative purposes only.
Bakri SJ, et al. *Plos One*. 2024;19(6):e0304782. Patel S, et al. *Ophthalmol Sci*. 2024;4(5):100527. Wykoff CC, et al. *J Vitreoretin Dis*. Sep-Oct 2024;8(5):577–586.

DAVIO 2 Phase 2 Trial Evaluated EYP-1901 vs Aflibercept for Previously-Treated nAMD

Study Design



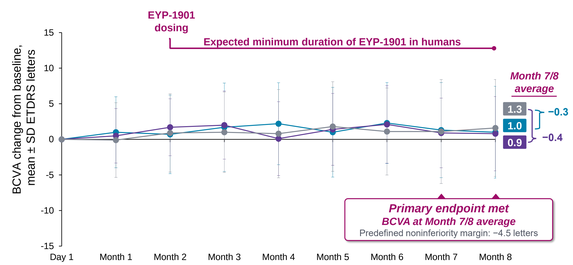
Protocol prespecified criteria[a]

- BCVA reduction ≥5 letters *and* CST increase ≥75 µm
- CST increase ≥100 µm
- BCVA reduction ≥10 letters
- Vision threatening hemorrhage

Investigator discretion

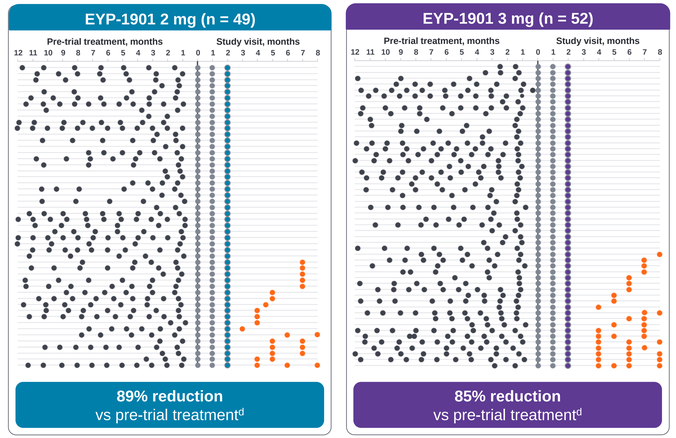
Primary Endpoint Met

BCVA change from baseline



Substantially Reduced Treatment Burden

63% of eyes receiving EYP-1901 were supplemental injection–free up to Week 32[c]



Baseline Characteristics

DAVIO 2 enrolled previously-treated patients with nAMD

Baseline characteristics were well-balanced across arms

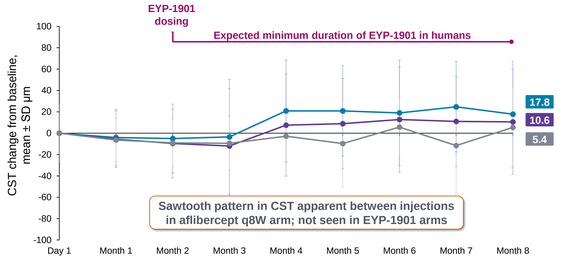
~10 anti-VEGF injections in past year *normalized mean;*[b] *range 2–13 injections*	**~20/32 Snellen equivalent** *mean 73–75 ETDRS letter score; range, 41–85 letters*
~2 years since diagnosis *mean; range, 0.1–20 years*	**~263–266 µm CST** *mean; range, 178–400 µm*

Favorable Safety Profile

- 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

Strong Anatomical Control

CST change from baseline



DAVIO 2 Met Its Primary Endpoint

In the **largest completed trial** of an intravitreal TKI to date, EYP-1901 demonstrated **non-inferiority** to aflibercept with **stable BCVA**, a **favorable safety profile**, and **reduced treatment burden**

[a] Due to wet AMD; from best on-study measurement. [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. [c] Actual injections received; i.e., does not include visits where eyes met criteria but no injection given per investigator discretion. [d] 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.

Phase 3 Now Enrolling

LUGANO & LUCIA

NCT06668064 NCT06683742

Phase 3 global, randomized, double-masked, aflibercept-controlled clinical trials for ~800 patients with active nAMD

Objective:
Demonstrate that EYP-1901, when administered every 6 months, achieves similar visual outcomes to aflibercept 2.0 mg q8W while reducing treatment burden in patients with active nAMD

Presented at the Royal College of Ophthalmologists Annual Congress May 19–22, 2025 | Liverpool, UK

Please visit eyepointpharma.com for more information

Study Disclosures

DAVIO 2 Clinicaltrials.gov Identifier: NCT05381948. DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU™ is an investigational product; it has not been approved by the FDA. These data are preliminary. Conclusive evidence of efficacy and safety of EYP-1901 will require further investigation in well-controlled Phase 3 clinical trials.

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Author Disclosures

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Abbreviations

ANG, angiopoietin; **AAV**, adeno-associated virus; **BCVA**, best-corrected visual acuity; **CST**, central subfield thickness; **D**, day; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **nAMD**, neovascular age-related macular degeneration; **PDGF(R),** Platelet-derived growth factor (receptor); **PLGF**, placental growth factor; **q8W**, every 8 weeks; **SAEs**, serious adverse events; **VEGF(R),** vascular endothelial growth factor (receptor); **W**, week.