8-month Results of a Tyrosine Kinase Inhibitor (Vorolanib) in a Bio-erodible Durasert® Implant for Previously Treated Wet AMD: The DAVIO Trial

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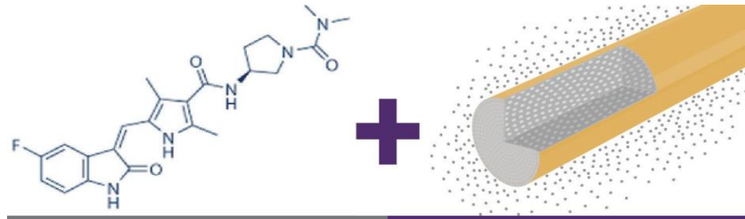

Financial Interest Disclosure – Jay S. Duker, M.D.

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- EyePoint Pharma

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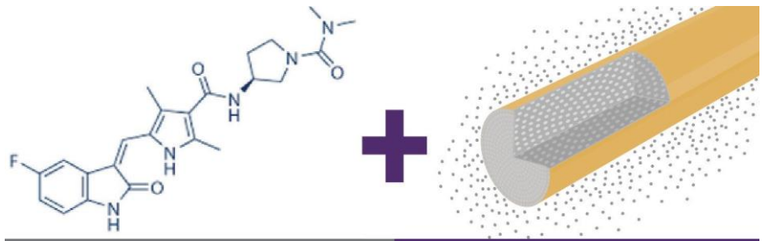
DAVIO Take Home Messages:
EYP-1901 Phase 1 Clinical Trial Met All Objectives

All objectives successfully met: Proof of Concept for Vorolanib in wet AMD



SAFETY

Positive Safety Data

- No ocular SAEs reported
- No drug-related systemic SAEs reported
- Ocular AEs - majority mild and to be expected

EFFICACY and DURABILITY

Positive Efficacy Data

- Stable VA and OCT
- Median time to supplemental anti-VEGF: 6 months

- **76 %** rescue-free up to 4 months
- **53 %** rescue-free up to 6 months
- **41 %** rescue-free up to 9 months

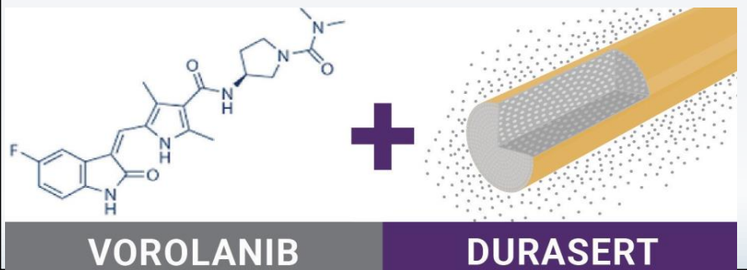
- Clinically significant reduction in treatment burden by **79 %** at six mo – **75 %** at 8 mo

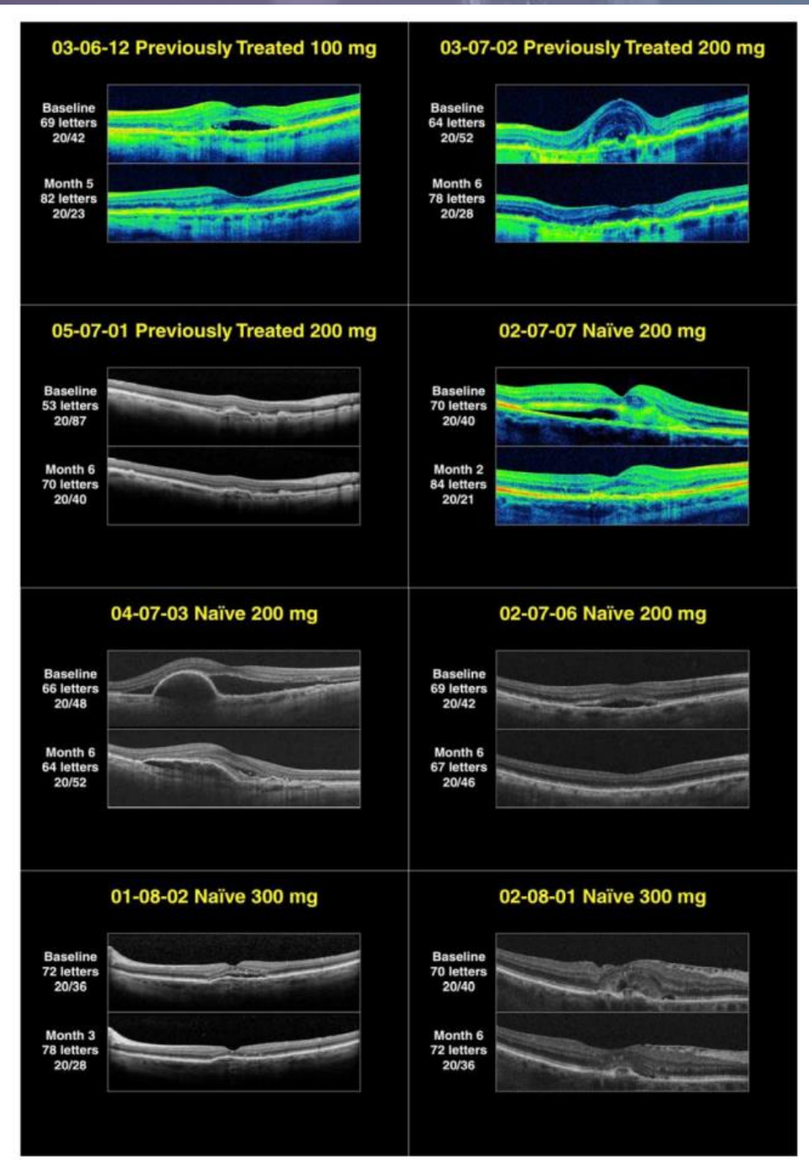
EYP-1901 – Vorolanib in Bio-erodible Durasert

A Novel Approach to Wet AMD Therapy

Vorolanib as an Oral Therapy

- Receptor-binding, small molecule tyrosine kinase inhibitor (TKI)
- Activity against all isoforms of VEGF and PDGF
- Oral vorolanib previously studied in a wet AMD ph1 and ph2 programs[1,2]
  - Strong efficacy signal but systemic toxicity halted the ph2 study
  - **No ocular toxicity noted**

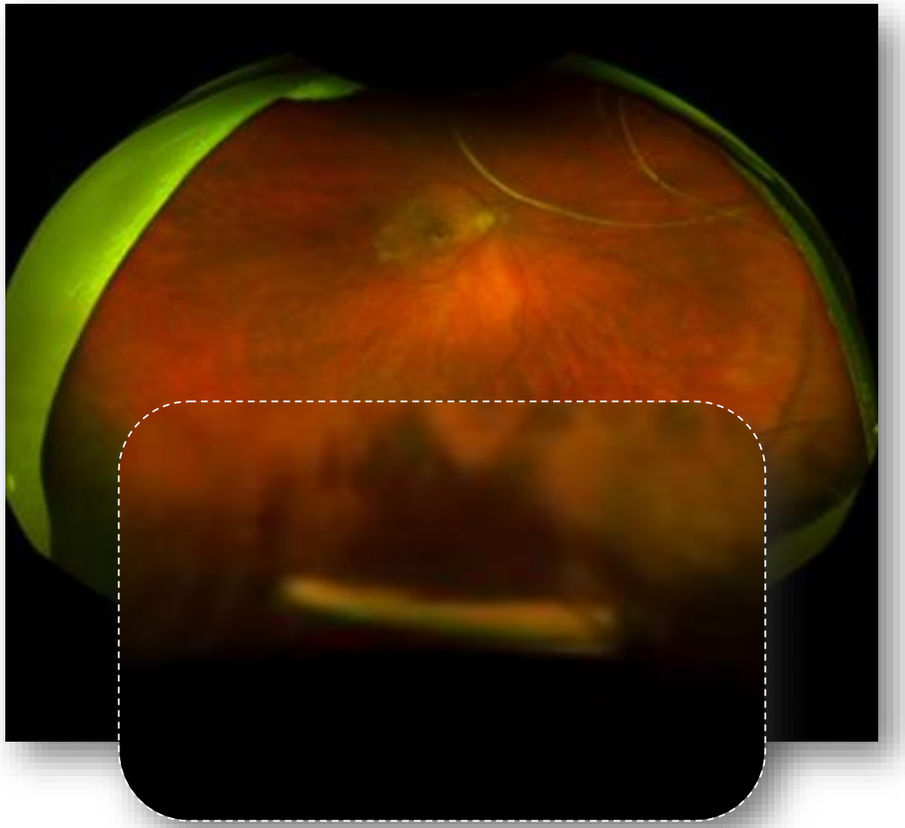




1. Jackson et al. JAMA Ophthalmol 2017
2. Cohen MN et al. Br J Ophthalmol. 2021

EYP-1901 – Vorolanib in Bioerodible Durasert

A Novel Approach to Wet AMD Therapy



EYP-1901 insert at month 5 post-injection

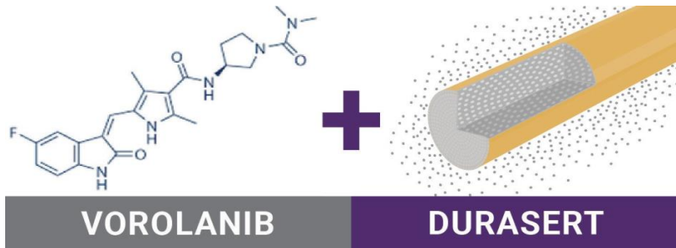
Bioerodible Durasert® Platform: injectable, sustained-delivery technology

Similar to YUTIQ®, Retisert®, and Vitrasert®

- Main difference:
  No polyimide shell ---> Bioerodible

Drug release dynamics

- Initial burst from surface of implant
- Constant, zero-order kinetic release rate for months
- Designed for approximately six month or longer efficacy



DAVIO - Durasert and Vorolanib In Ophthalmology - Wet AMD

Phase 1 Trial. Open label, Dose Escalation, No Control Arm

Enrollment

- Previously treated wet AMD eyes only
- No exclusion for presence of fluid

NO EYP-1901 retreatments

Criteria for supplemental anti-VEGF therapy*:

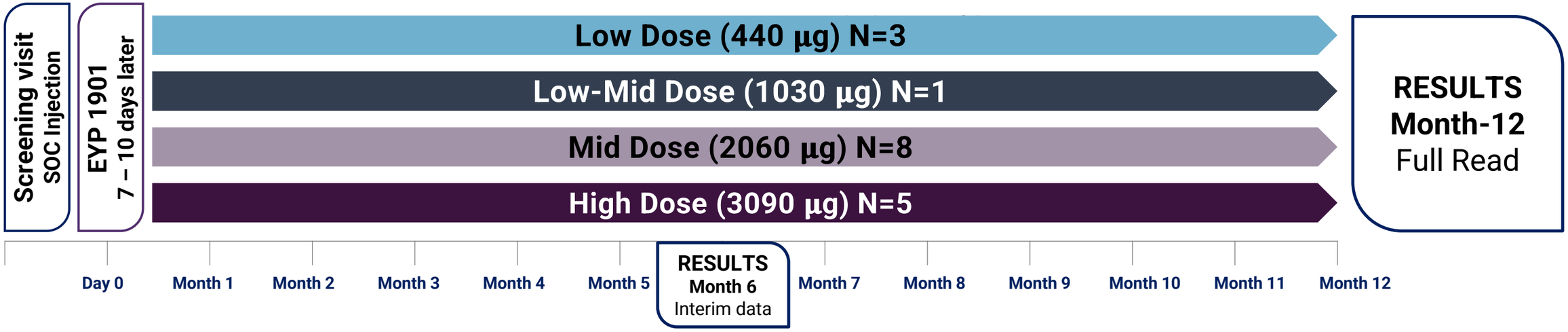
- New fluid > 75 microns (OCT) compared to Day-0
- ≥ 2 lines of BCVA secondary to wet AMD compared to Day-0
- New macular hemorrhage secondary to wet AMD

Primary endpoint: safety

- Interim at month-6
- Full readout at month-12

Secondary endpoints:

- BCVA
- CST as measured by OCT



Note: All doses delivered in a single intravitreal injection.
BCVA: best corrected visual acuity; OCT: optical coherence tomography; CST: central subfield thickness

EYP-1901 Phase 1 DAVIO Participants

Screening Characteristics (N=17)	
Mean age, range (years)	77.4 (67–94)
Female (n, %)	13/17 (76%)
Mean BCVA, range (ETDRS letters)	69 letters, (38-85)
Mean CST, range (microns)	299 microns, (204–441)
Median length of time for wet AMD diagnosis prior to enrollment	17 months
Mean # of injections per year prior to enrollment	8.76 injections/year

BCVA: best corrected visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; CST: central subfield thickness

DAVIO Primary Endpoint – Safety Up to 8 months

Positive Overall Safety Data

No ocular serious adverse events (SAEs) reported
No drug-related systemic SAEs reported

Ocular AEs of particular interest:

- No vitreous floaters
- No endophthalmitis
- No retinal detachment
- No implant migration in the anterior chamber
- No retinal vasculitis
- No posterior segment inflammation

Ocular AEs Observed:

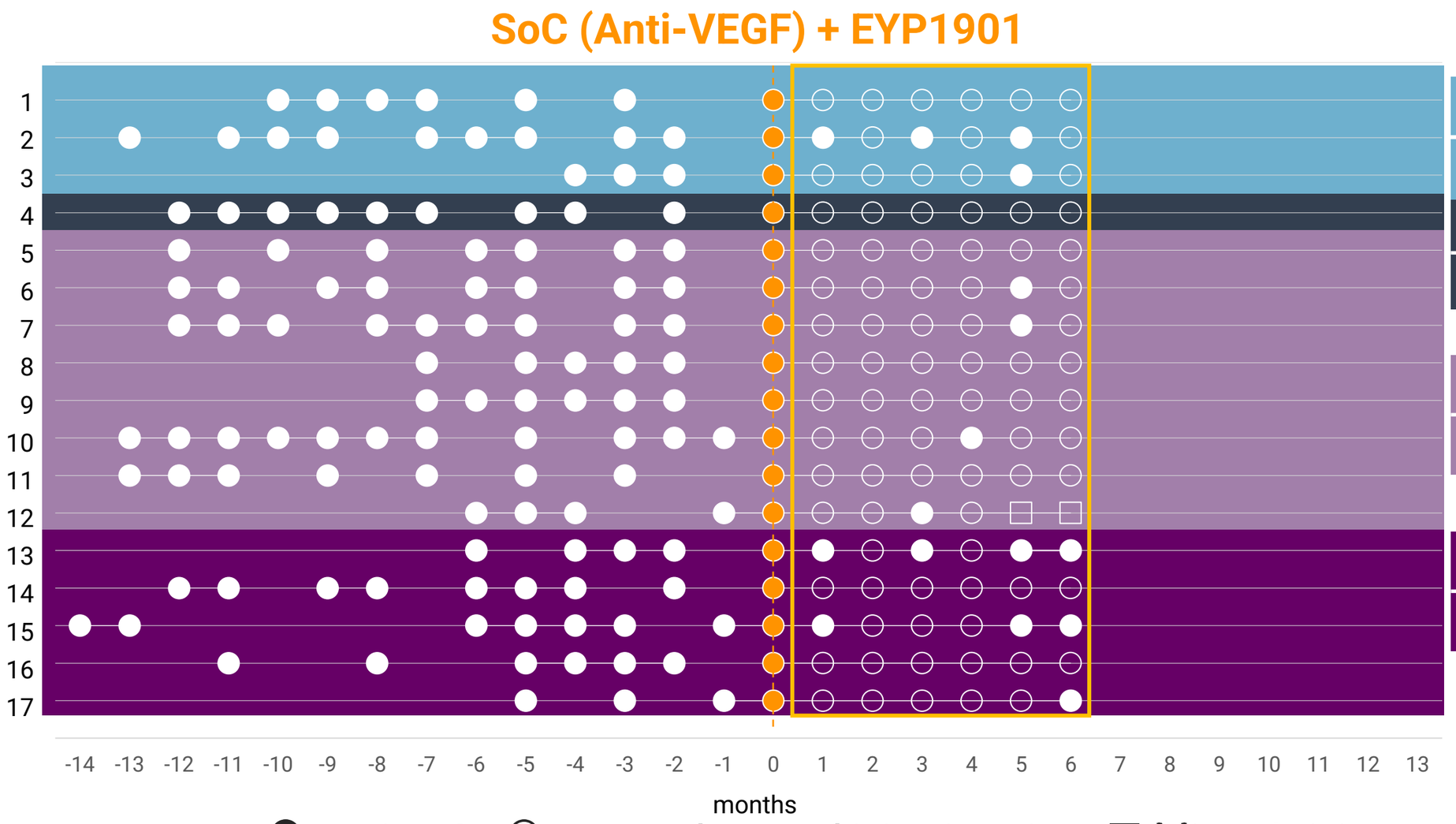
- One eye: mild asymptomatic anterior chamber cell/flare; *Treated with Maxitrol® eyedrops – resolved in 8 days –no sequelae or recurrence*
- One eye: asymptomatic vitreous hemorrhage from injection; *Observed*

AC, anterior chamber; AE, adverse event; BCVA, best corrected visual acuity; SAE, serious adverse event

Clinically Significant Reduction in Treatment Burden - *79 % at Six Months*

EYP-1901 Phase 1 DAVIO Study –

SOC Anti-VEGF Injections Before and After Treatment



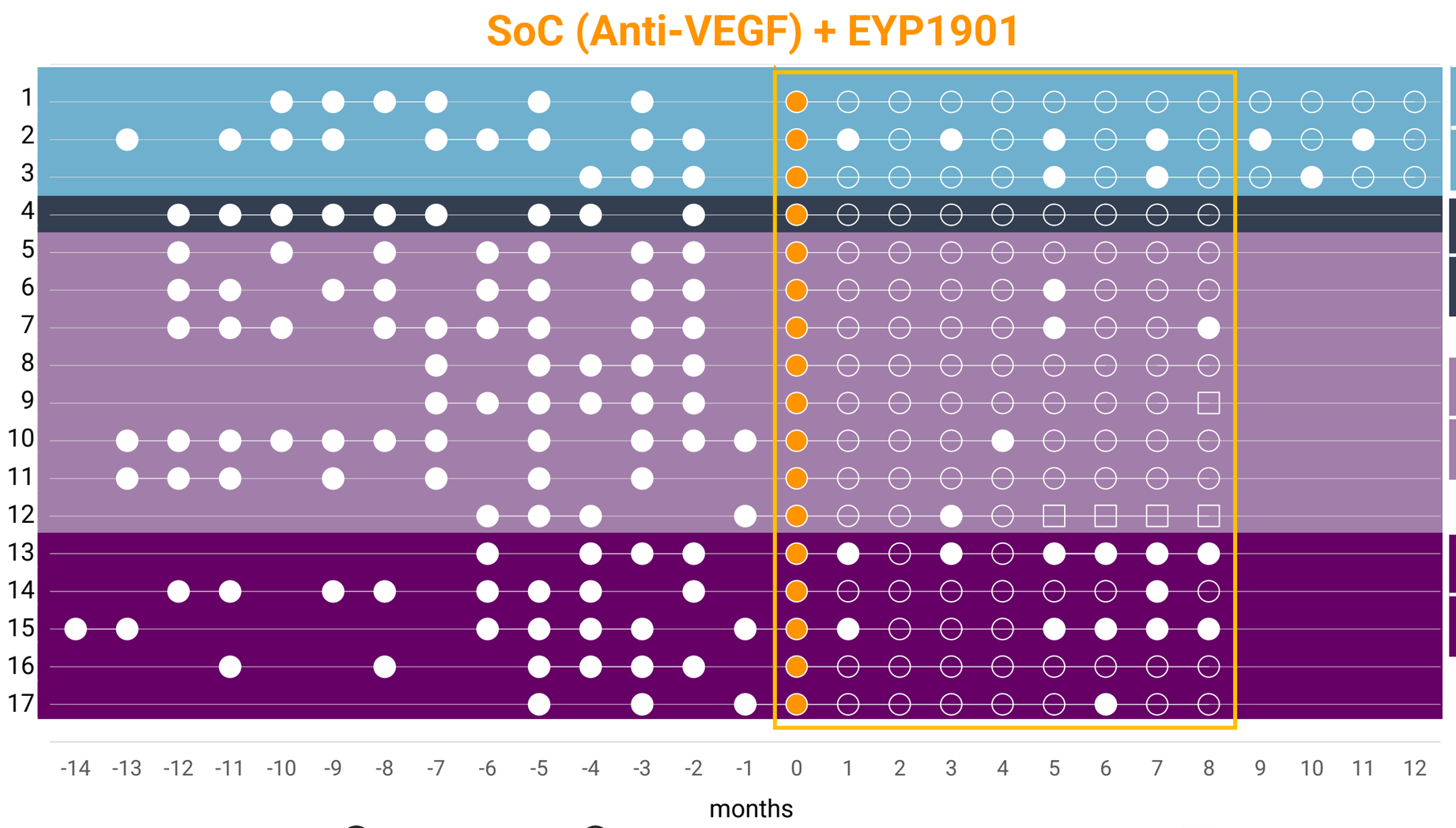
Reduction in Average Monthly Tx Burden at 6 mos

Low dose (n=3)	- 70%
Low-mid dose (n=1)	- 100%
Mid dose (n=8)	- 89%
High dose (n=5)	- 55%

Interim data – monitored through 6 months

Clinically Significant Reduction in Treatment Burden - *75 % at 8 Months*
EYP-1901 Phase 1 DAVIO Study

SOC Anti-VEGF Injections Before and After Treatment



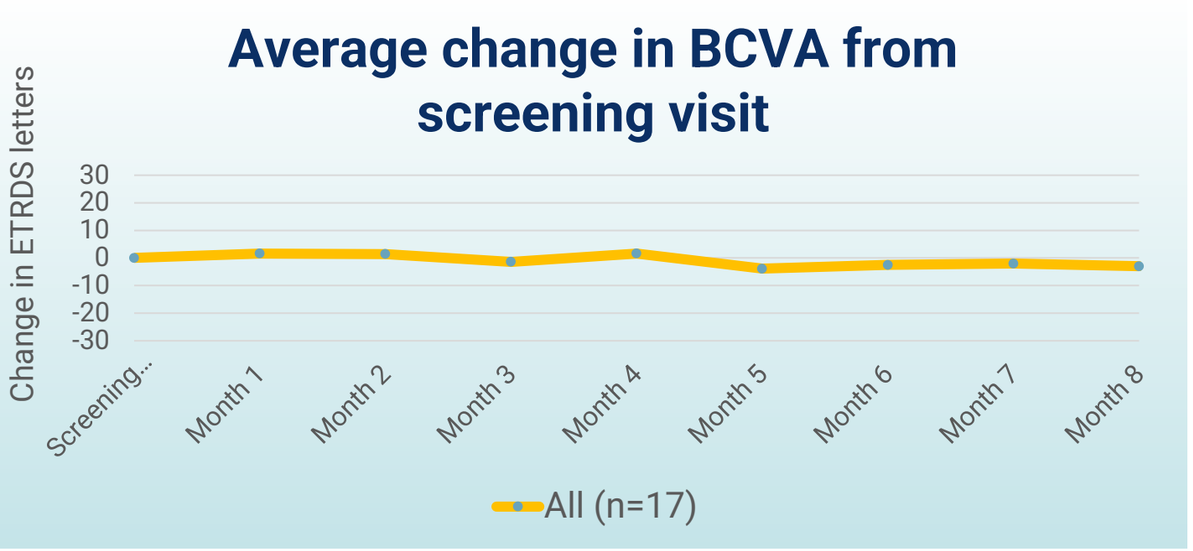
Reduction in Average Monthly Tx Burden at 8 mos

Low dose (n=3)	- 66 %
Low-mid dose (n=1)	- 100%
Mid dose (n=8)	- 90 %
High dose (n=5)	- 50 %

Interim data – monitored through 6 months

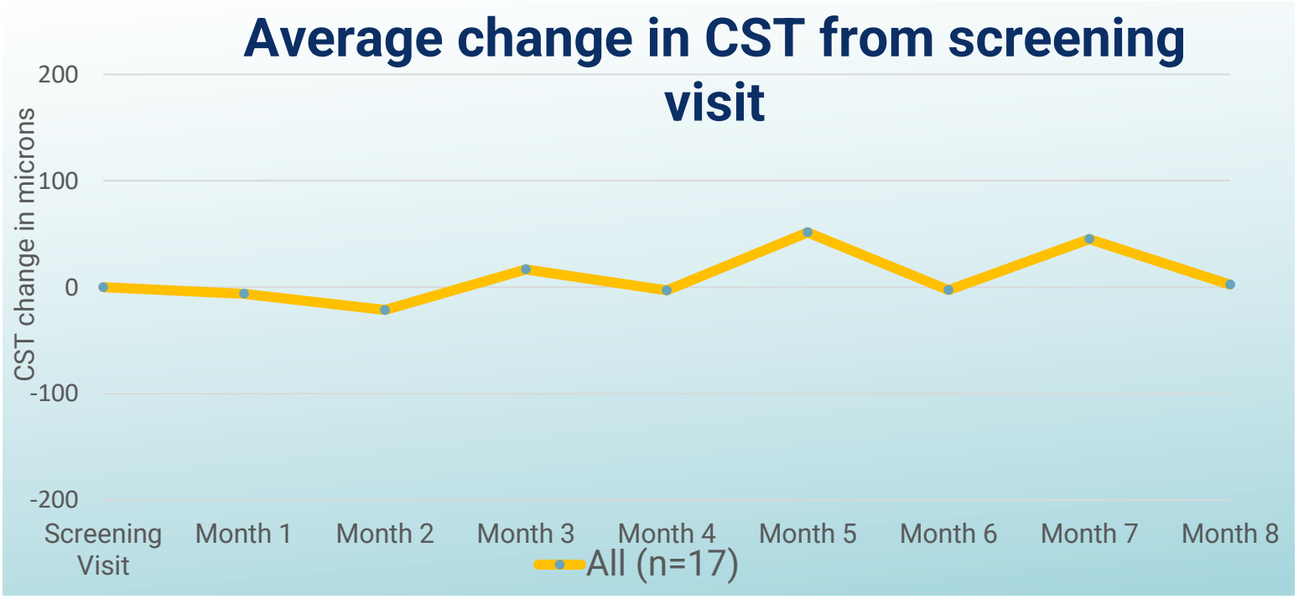
Results: *Average Visual Acuity (VA) and Central Subfield Thickness (CST) Stable - 8 Months After Single Treatment*

For all 17 eyes at 8 months
VA = -3.0 letters



BCVA: best corrected visual acuity

For all 17 eyes at 8 months
CST on OCT = + 2.4 microns

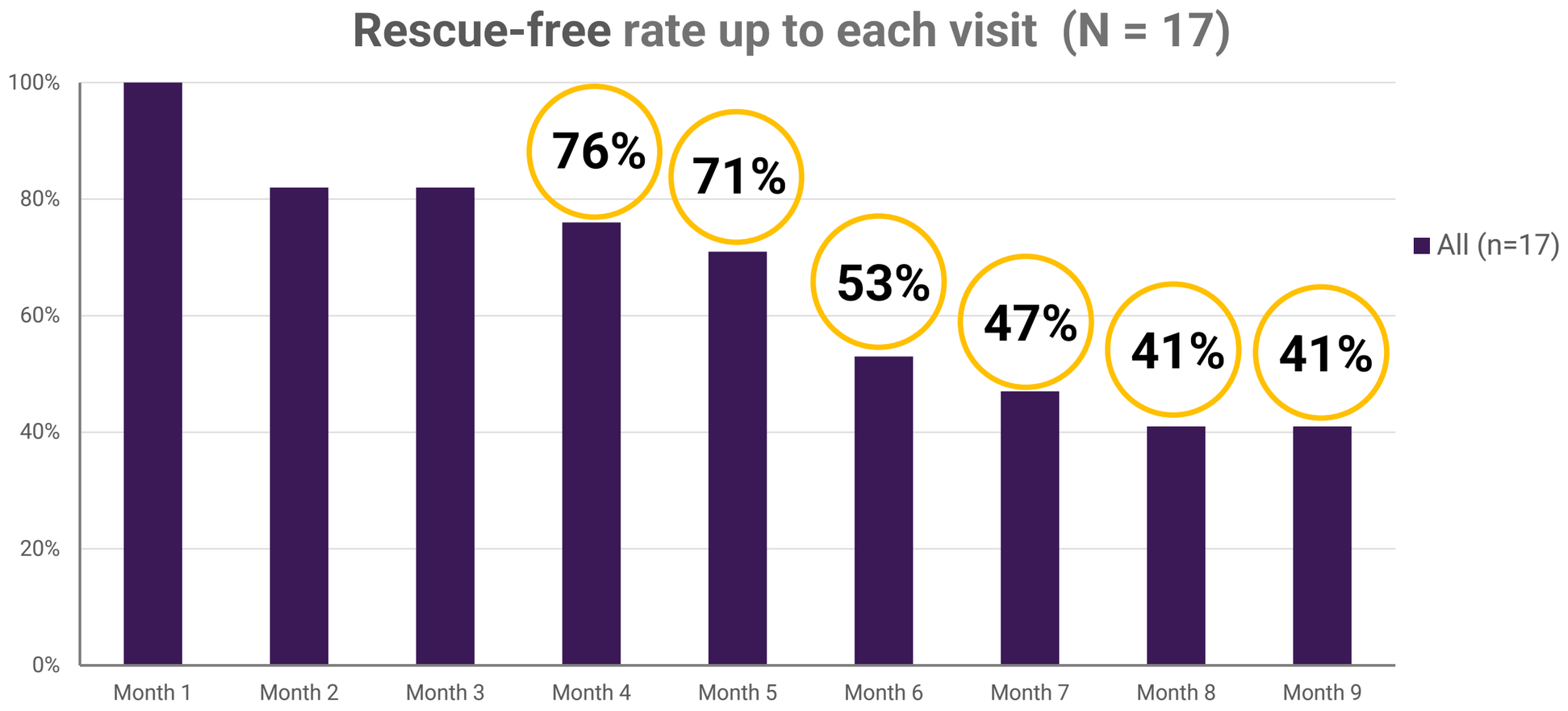


OCT: optical coherence tomography; CST: central subfield thickness

Interim data – monitored through 6 months

Rescue-free Rates Up to Each Visit: Entire Study Group

Median Time to supplemental anti-VEGF = 6 Months



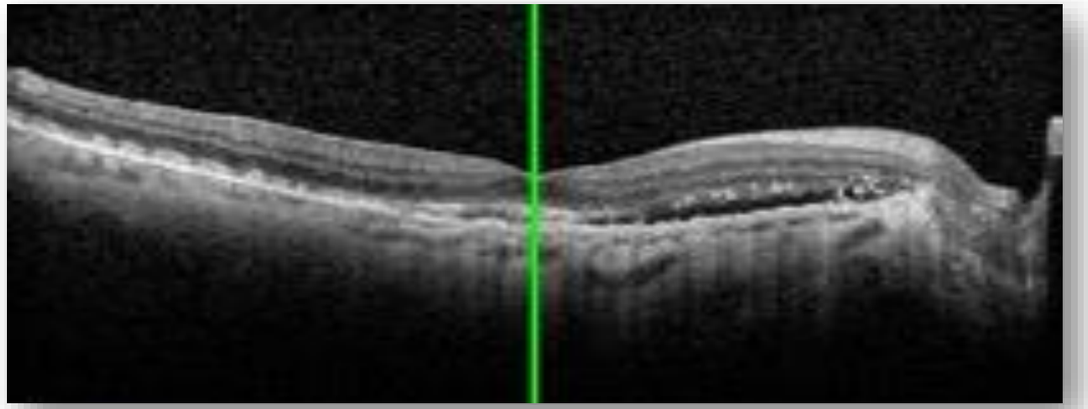
Interim data – monitored through 6 months

Patient 1: Entered Dry, Stayed Dry for 12 Months with No Supplemental anti-VEGF

Low dose cohort (EYP-1901 440 µg)

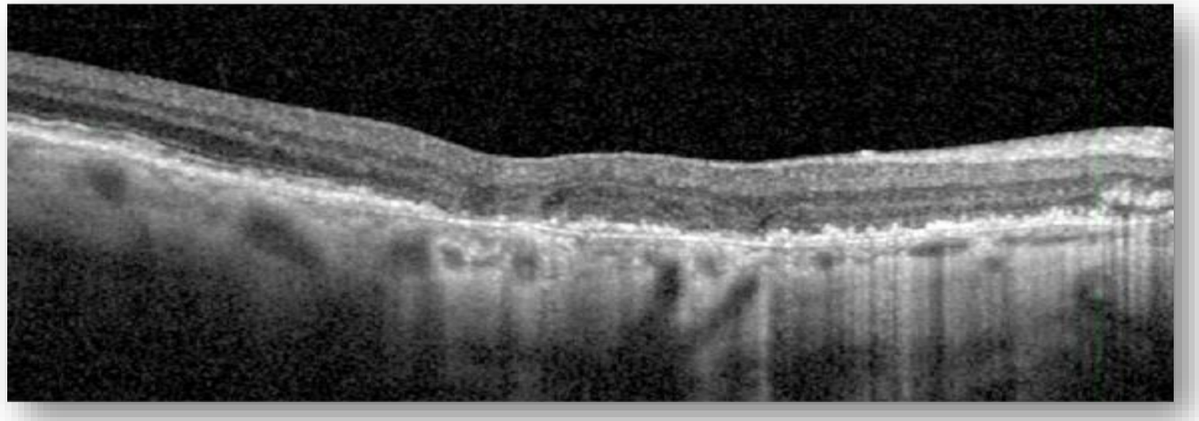
Initial Diagnosis 9 mo before enrollment

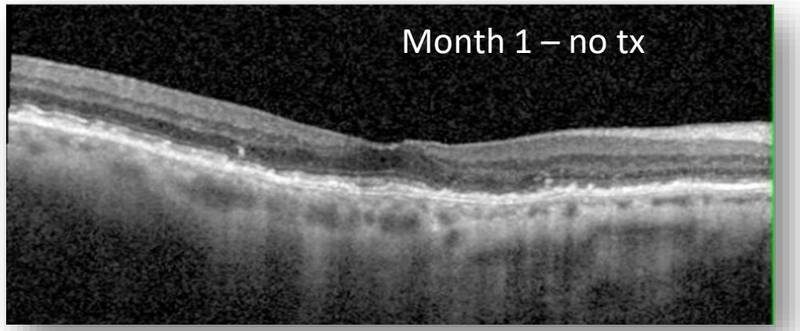
Initial Diagnosis: *9 months prior to enrollment*

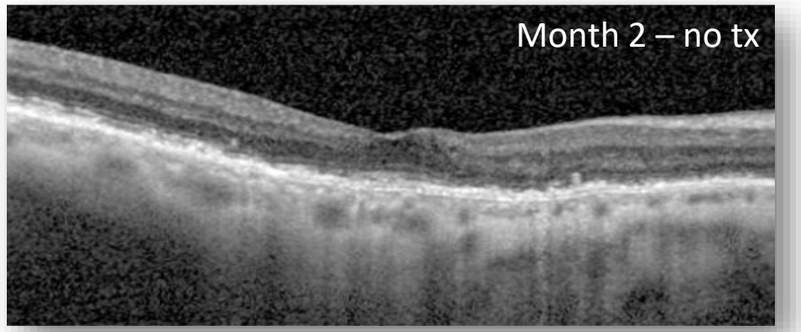


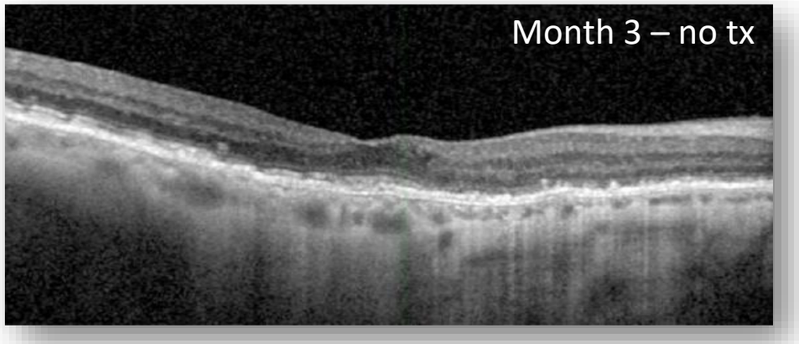
Screening visit prior to treatment

Screening Visit: *6 anti-VEGF injections prior to enrollment*



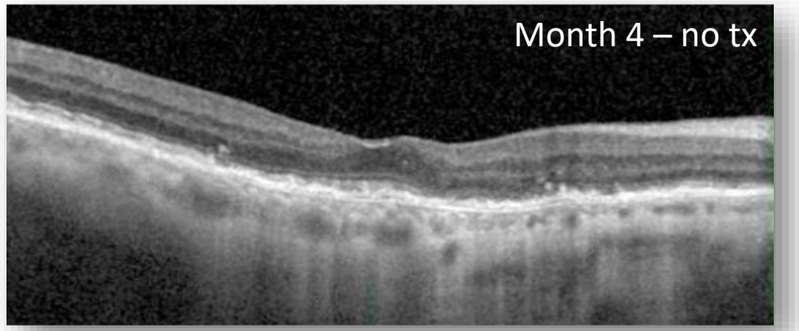


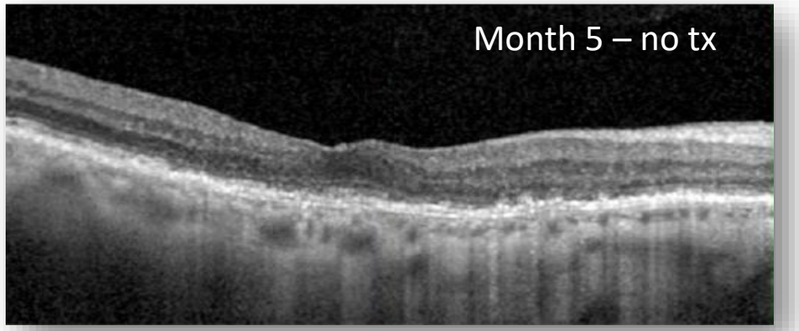


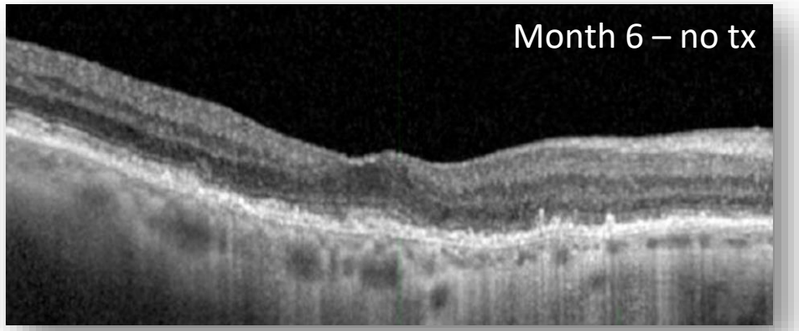


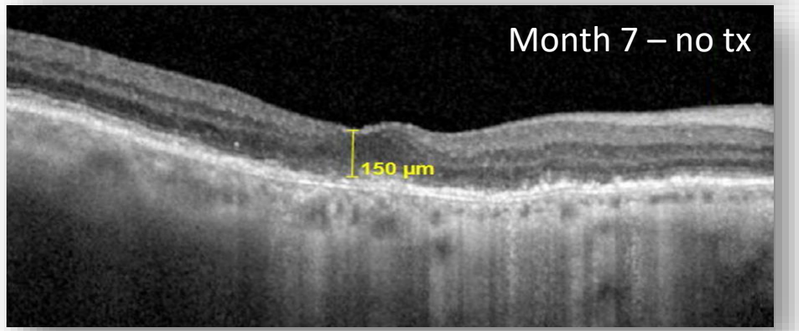
Patient 1: Post-Treatment - No Supplemental Anti-VEGF Through Month 12

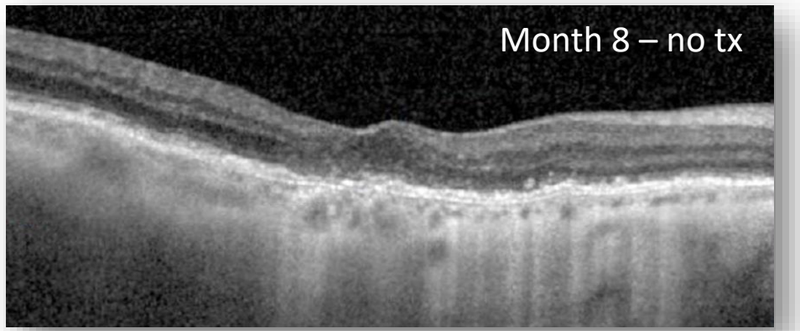
Low dose cohort (EYP-1901 440 µg)

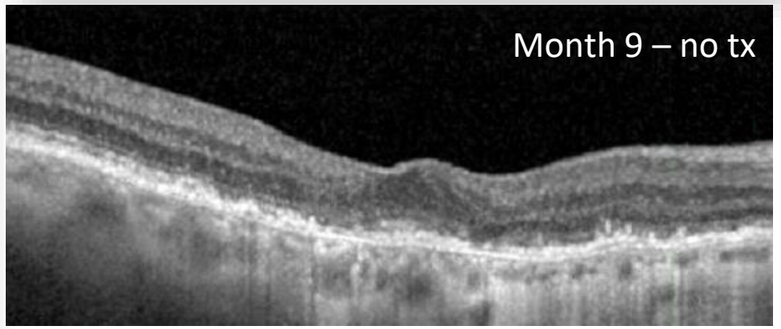


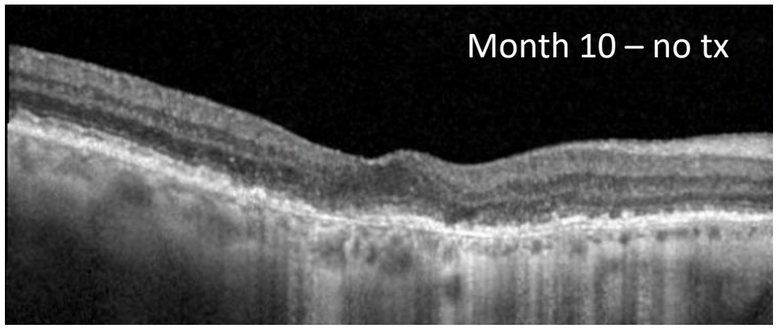


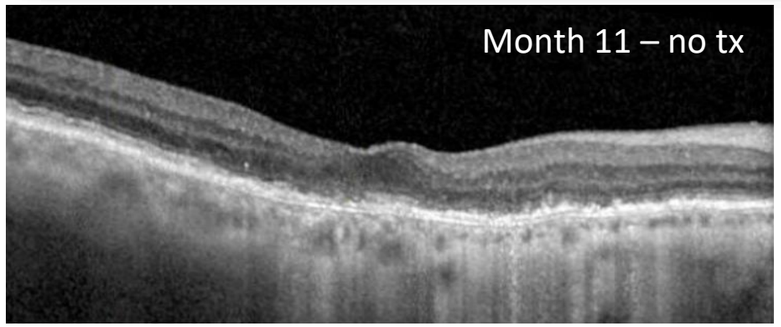


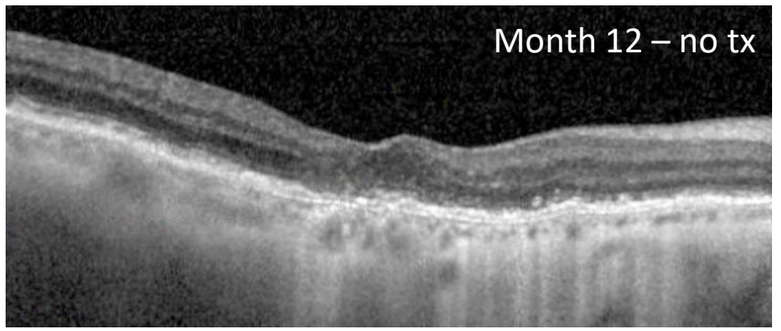










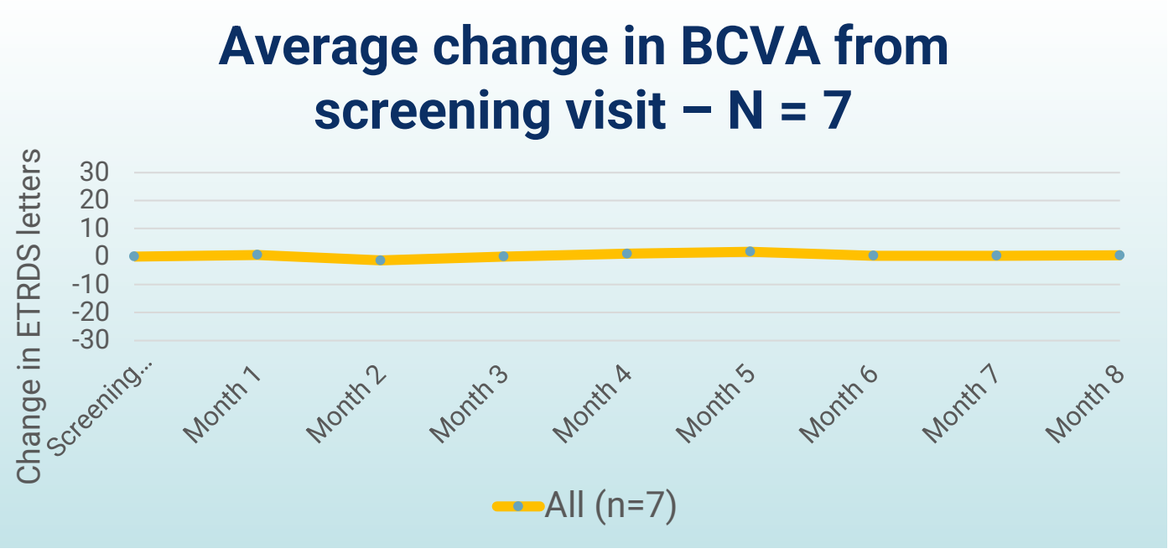


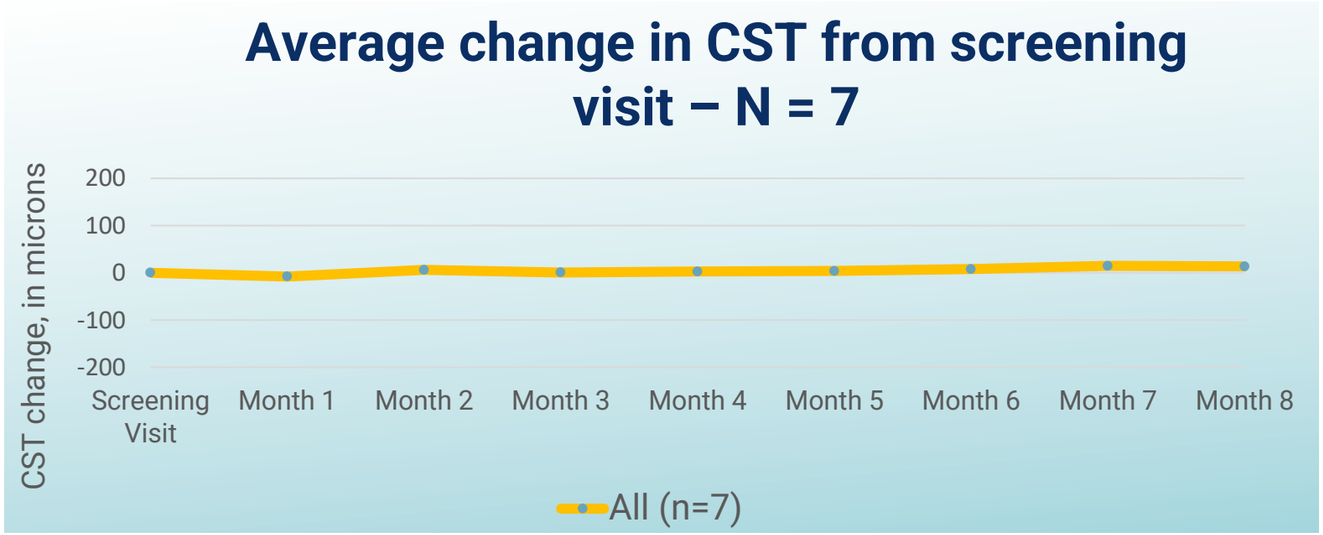
At 8 months follow up, 7 of 17 (41 %) Eyes Rescue-Free

VA and CST both stable for these 7 eyes

For all 7 eyes at 8 months
VA = +0.4 letters

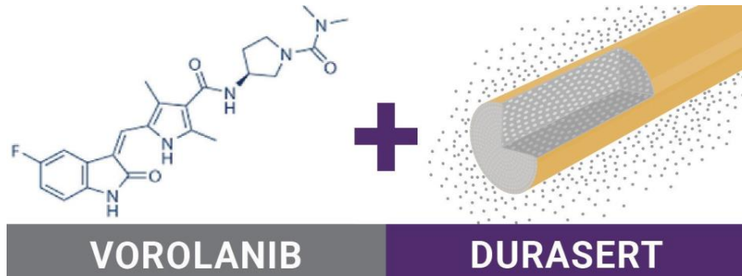
For all 7 eyes at 8 months
CST on OCT = +13.6 microns



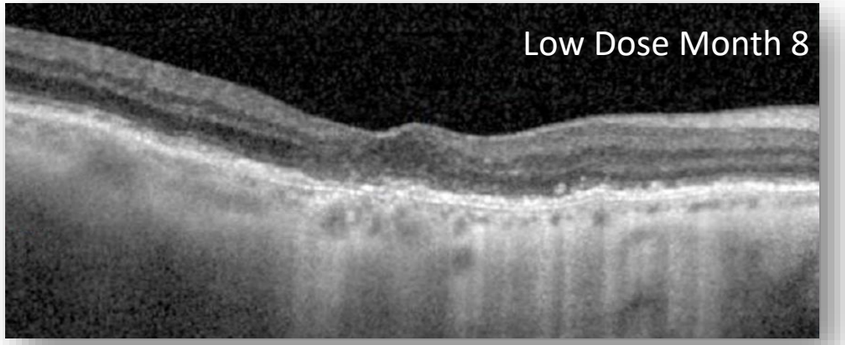


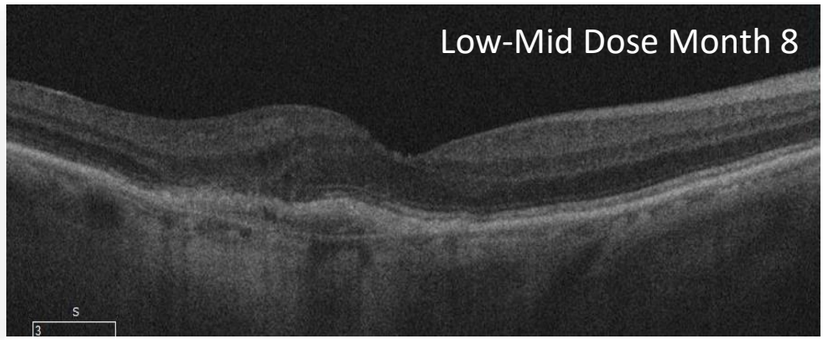
BCVA: best corrected visual acuity

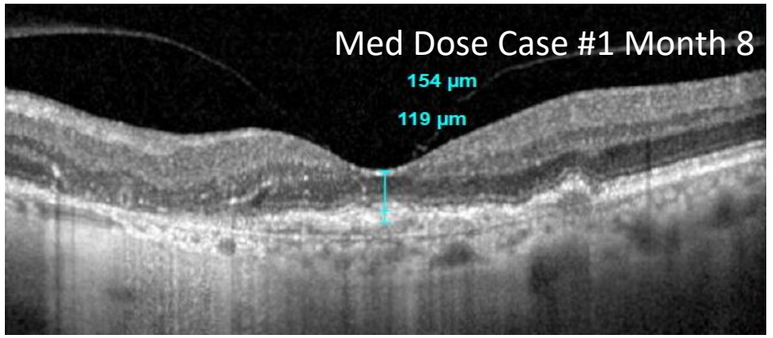
Interim data – monitored through 6 months

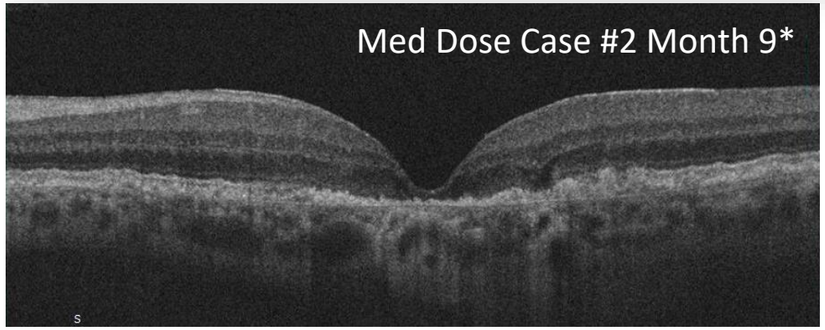


Longevity of Efficacy – At 8 months post EYP-1901, Six of Seven Unsupplemented Eyes Remain Dry

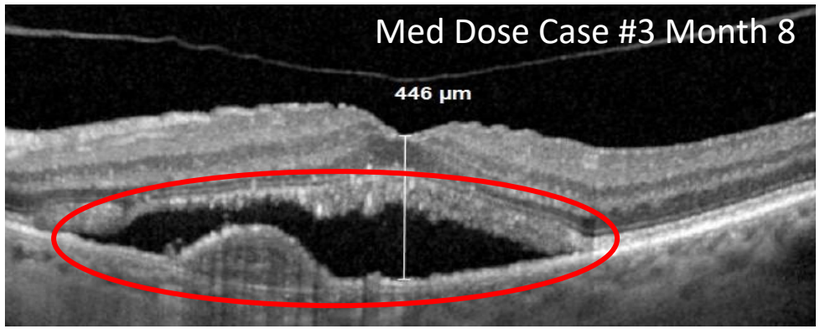


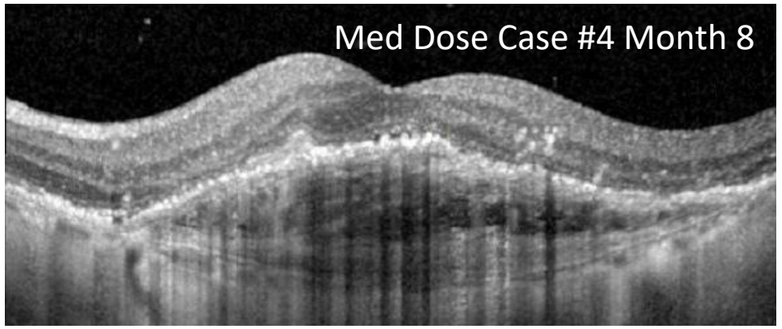


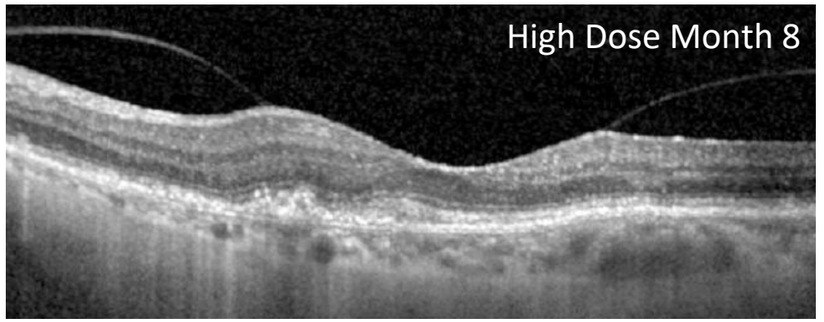


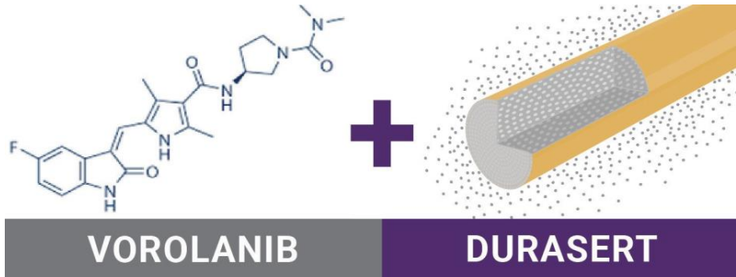


*Month 8 = missed visit



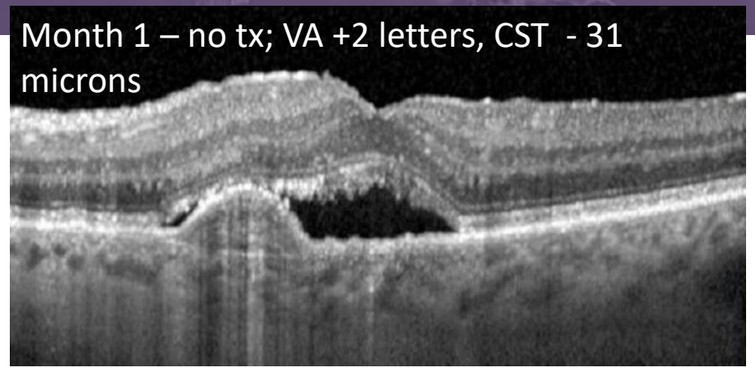


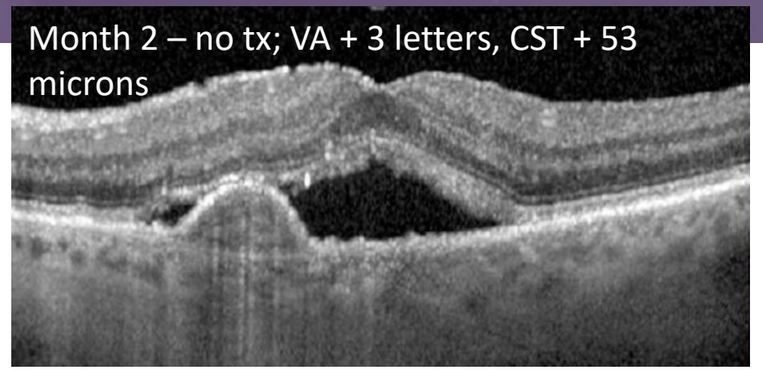


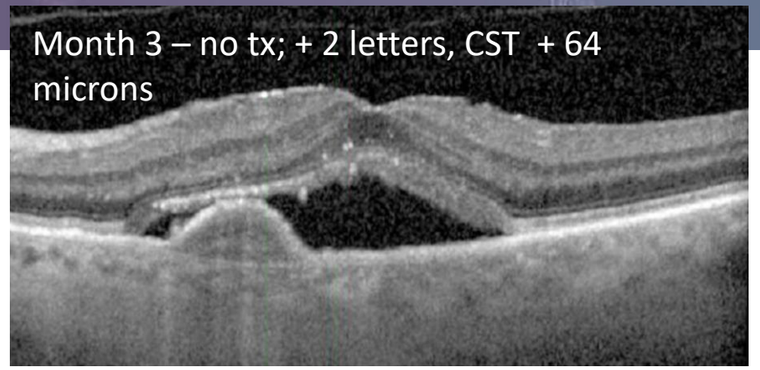


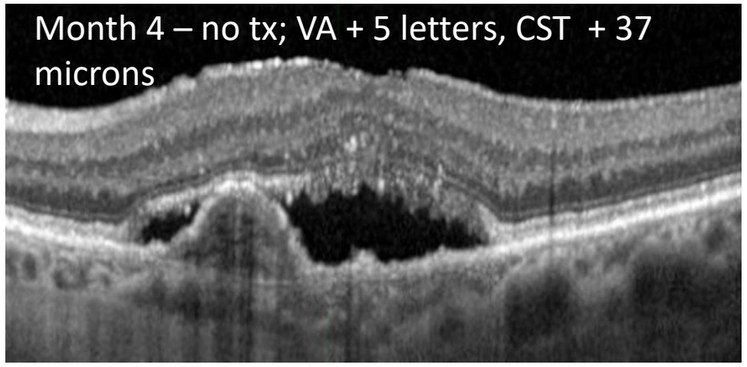
Unsupplemented Medium Dose Eye with Sub-retinal Fluid

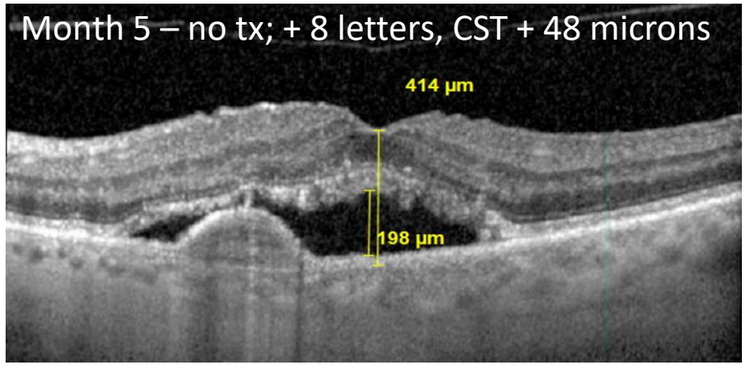
SRF Fluctuates while VA Improved

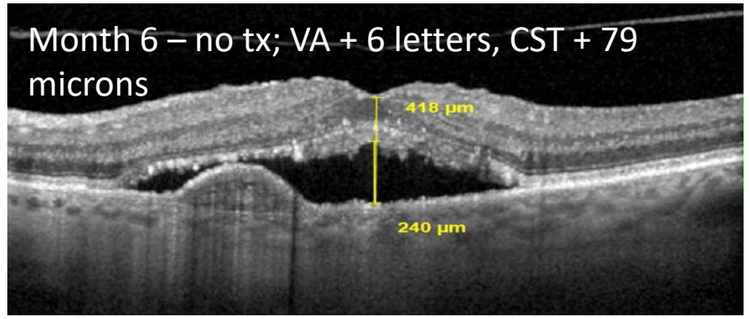


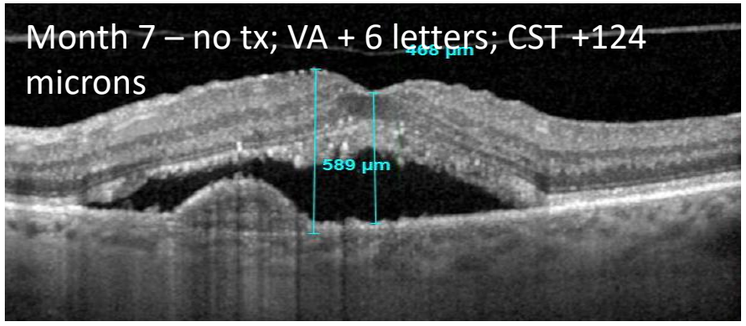


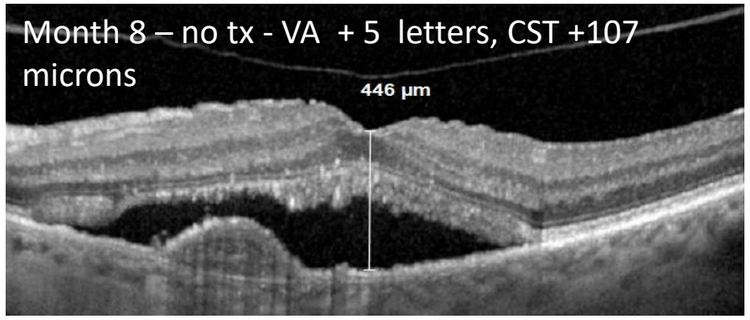


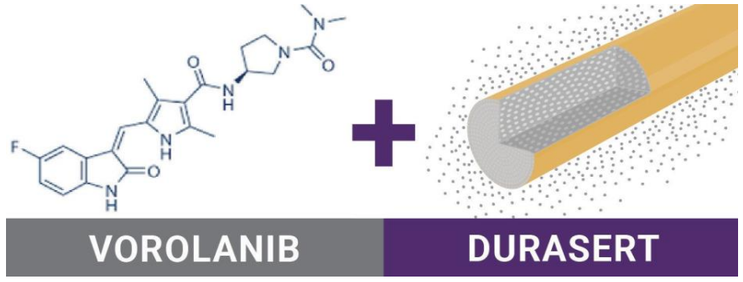






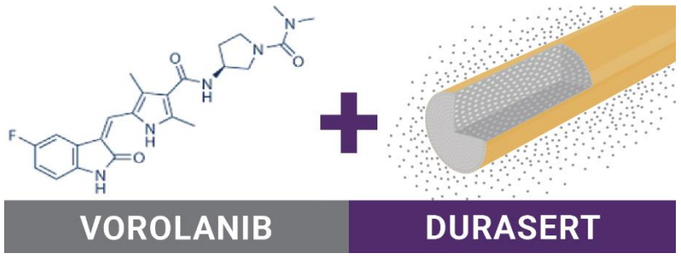






Next Steps for EYP-1901

EYP-1901



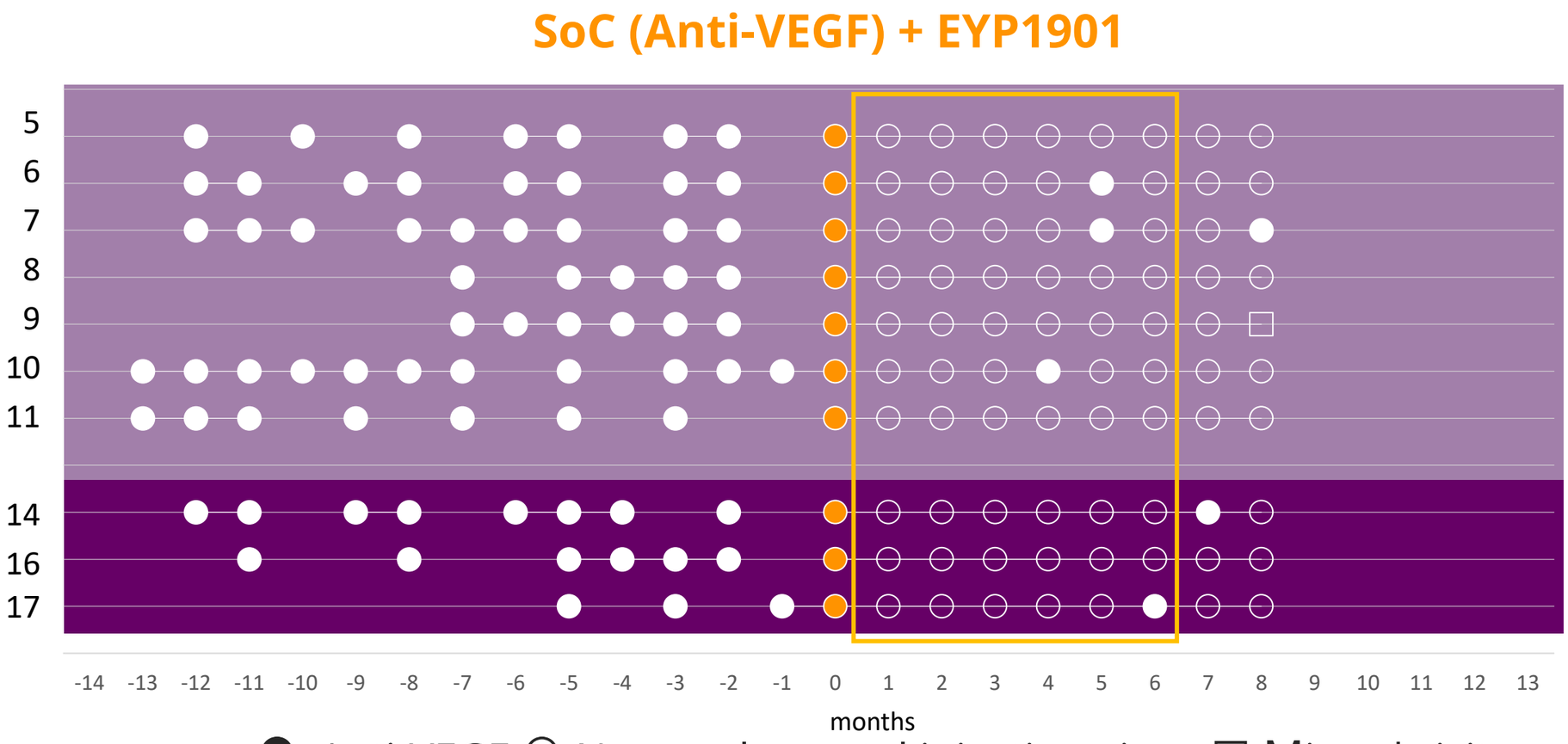
Three Phase 2 Trials Planned

- Advance EYP-1901 into three Phase 2 clinical trials by 2023
  - Wet AMD initiation expected in 3Q 2022
  - Diabetic Retinopathy initiation expected in 2H 2022
  - Third Indication - initiation expected by Q1 2023
- Wet AMD Trial Design
  - N = 144
  - 3 arms: EYP-1901 2 mg; EYP-190 3 mg; Eylea control
  - CST must be < 400 microns at screen (3-5 weeks post SoC)
  - No significant intraretinal fluid (IRF) at screen (3-5 weeks post SoC)

Retrospective DAVIO Sub-Group Analysis (N=10) Based on Potential Entry Criteria and Anticipated Dosing in Phase 2 Wet AMD Study – 89 % reduction in Treatment Burden at 8 months – 50 % unsupplemented up to month 9

Subgroup Analysis of DAVIO Medium & High Dose Patients – Using Proposed Ph2 OCT Entry Criteria

SOC Anti-VEGF Injections Before and After Treatment



Reduction in Treatment Burden of 89 % overall at 8 mos

Mid dose (n=7)

- 91%

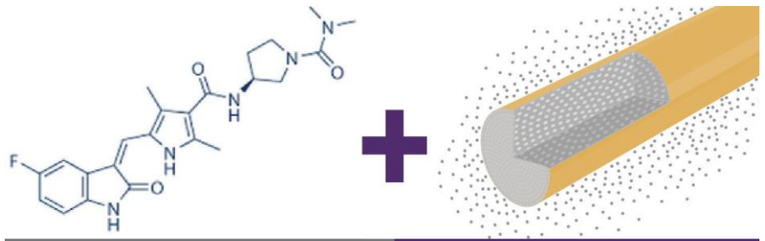
High dose (n=3)

- 85%

Interim data – monitored through 6 months

DAVIO Take Home Messages:
EYP-1901 Phase 1 Clinical Trial Met All Objectives

All objectives successfully met: Proof of Concept for Vorolanib in wet AMD



SAFETY

Positive Safety Data

- No ocular SAEs reported
- No drug-related systemic SAEs reported
- Ocular AEs - majority mild and to be expected

EFFICACY and DURABILITY

Positive Efficacy Data

- Stable VA and OCT
- Median time to supplemental anti-VEGF: 6 months

- **76 %** rescue-free up to 4 months
- **53 %** rescue-free up to 6 months
- **41 %** rescue-free up to 9 months

- Clinically significant reduction in treatment burden by **79 %** at six mo – **75 %** at 8 mo