

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): February 14, 2022

EyePoint Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-51122
(Commission
File Number)

26-2774444
(I.R.S. Employer
Identification No.)

480 Pleasant Street
Watertown, MA 02472
(Address of Principal Executive Offices, and Zip Code)

(617) 926-5000
Registrant's Telephone Number, Including Area Code
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	EYPT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On February 14, 2022, EyePoint Pharmaceuticals, Inc. posted an updated corporate presentation on its website at www.eyepointpharma.com. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation, dated February 14, 2022
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

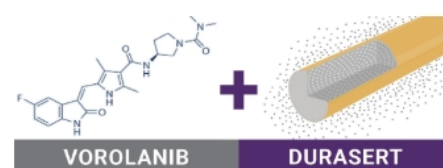
EYEPOINT PHARMACEUTICALS, INC.

Date: February 14, 2022

By: /s/ George O. Elston
Name: George O. Elston
Title: Chief Financial Officer

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

Jay S. Duker, M.D.
Chief Operating Officer
EyePoint Pharma



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

Employee

- EyePoint Pharma

Board of Directors

- Sesen Bio
- Hubble Tx

Consultant

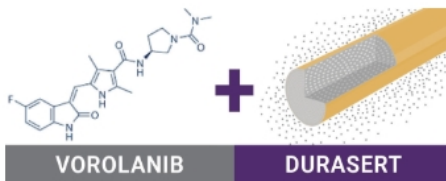
- Aura Bio
-

Forward looking statements

Various statements made in this presentation are forward-looking, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our expectations regarding the potential benefits of our partnerships and strategic alliances with other companies, as well as the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a vital, novel twice-yearly treatment for wet age-related macular degeneration, diabetic retinopathy and retinal vein occlusion; and our longer term financial and business goals and expectations, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the extent to which COVID-19 impacts our business; our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce sufficient commercial quantities of YUTIQ® and DEXYCU® and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for YUTIQ and DEXYCU; the development of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; the success of current and future license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; termination or breach of current license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of our stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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

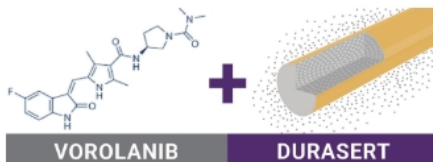
- Stable VA and OCT
- Median time to supplemental anti-VEGF: 6 months
- **76 %** rescue-free up to 4 months
- **53 %** rescue-free up to 6 months
- **41 %** rescue-free up to 9 months
- Clinically significant reduction in treatment burden by **79 %** at six mo – **75 %** at 8 mo

EYP-1901 – Vorolanib in Bio-erodible Durasert

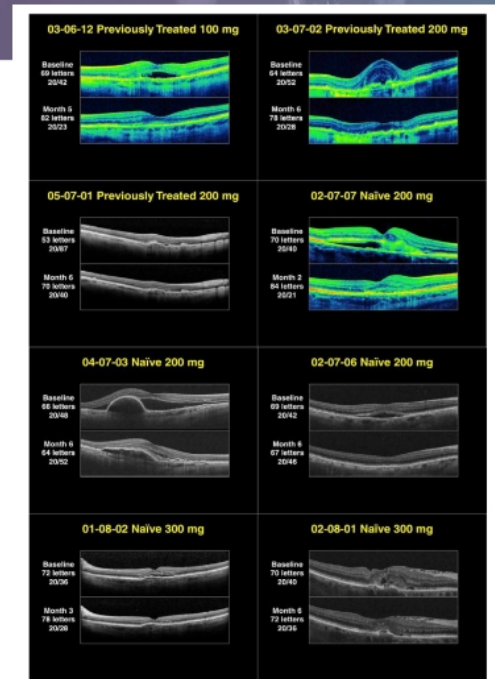
A Novel Approach to Wet AMD Therapy

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**

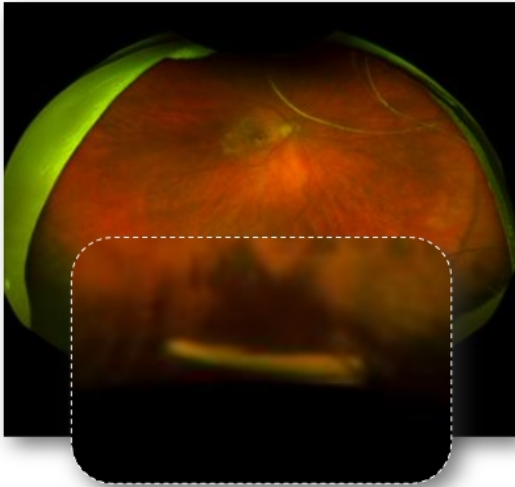


1. Jackson et al. JAMA Ophthalmol 2017
2. Cohen MN et al. Br J Ophthalmol. 2021



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*:

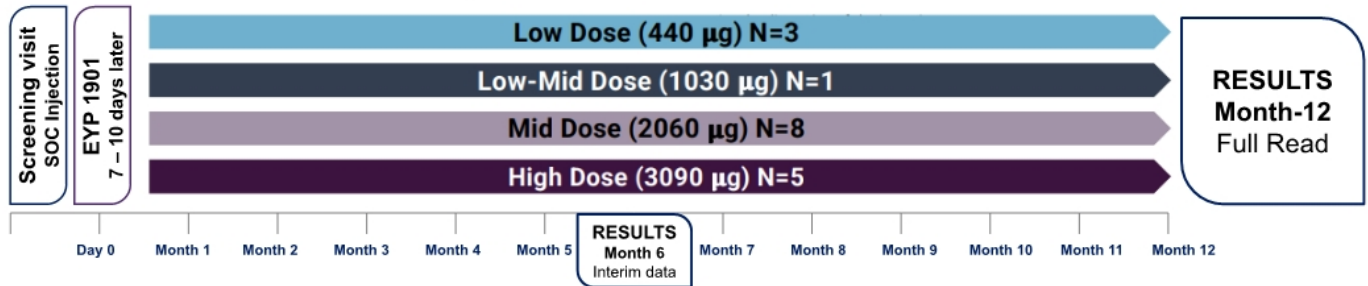
- New fluid > 75 microns (OCT) compared to Day-0
- ≥ 2 lines of BCVA secondary to wet AMD compared to Day-0
- New macular hemorrhage secondary to wet AMD

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*

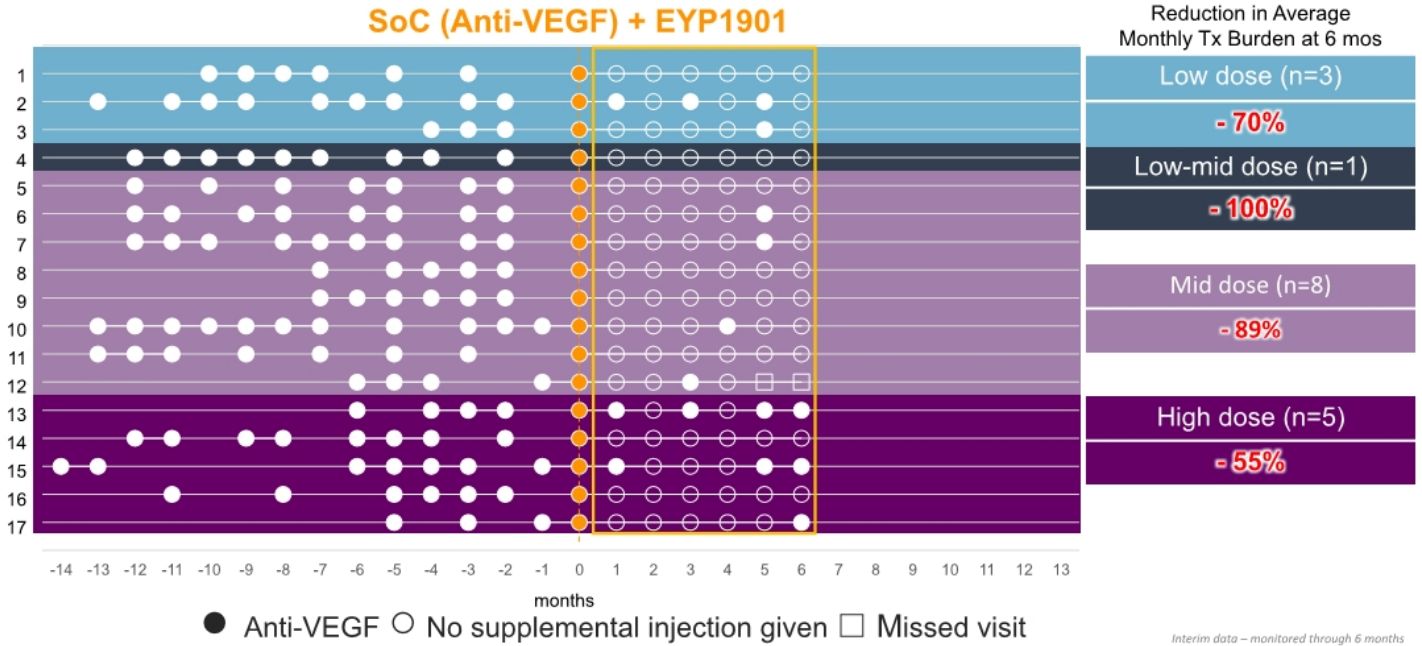
AC, anterior chamber; AE, adverse event; BCVA, best corrected visual acuity; SAE, serious adverse event

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

EYP-1901 Phase 1 DAVIO Study –

SOC Anti-VEGF Injections Before and After Treatment

SoC (Anti-VEGF) + EYP1901

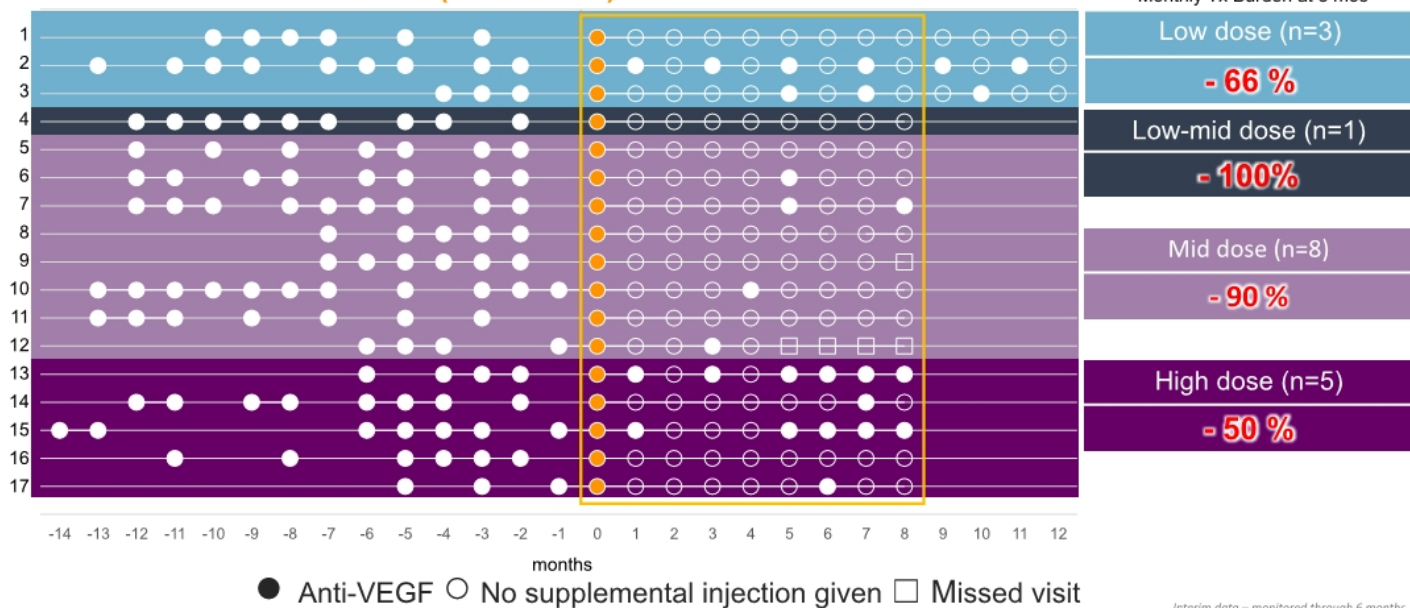


Clinically Significant Reduction in Treatment Burden - 75 % at 8 Months

EYP-1901 Phase 1 DAVIO Study

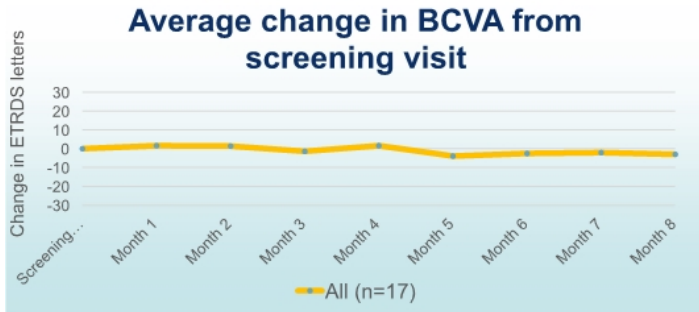
SOC Anti-VEGF Injections Before and After Treatment

SoC (Anti-VEGF) + EYP1901



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



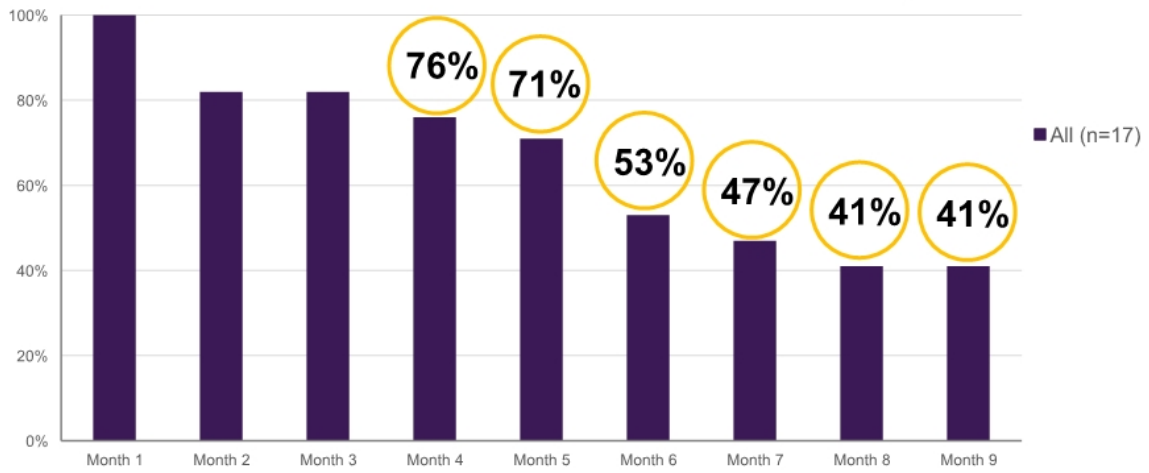
OCT: optical coherence tomography; CST: central subfield thickness

Interim data – monitored through 6 months

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

Median Time to supplemental anti-VEGF = 6 Months

Rescue-free rate up to each visit (N = 17)



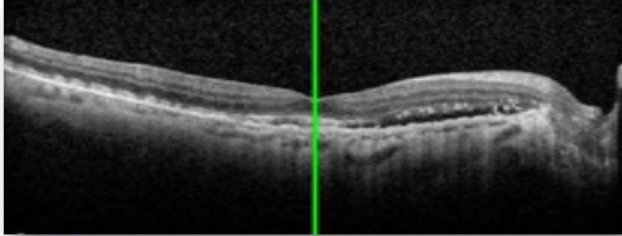
Interim data - monitored through 6 months

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

Low dose cohort (EYP-1901 440 µg)

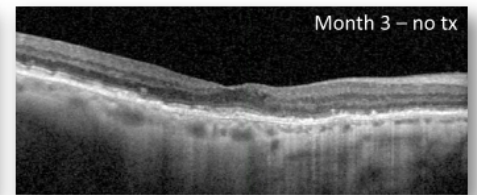
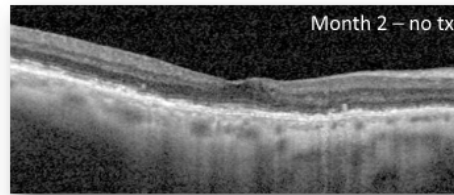
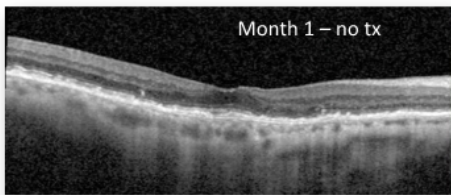
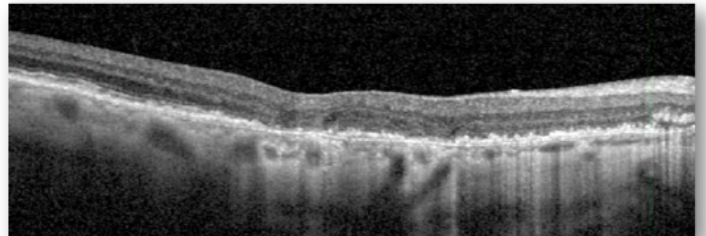
Initial Diagnosis 9 mo before enrollment

Initial Diagnosis: 9 months prior to enrollment



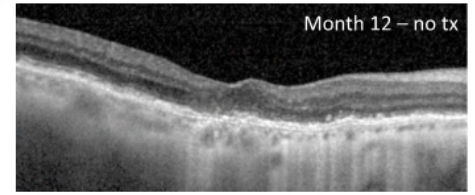
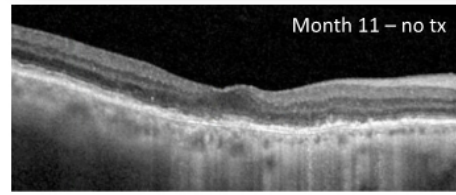
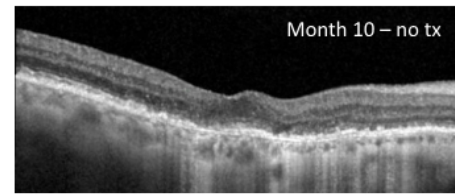
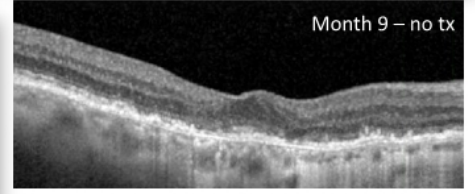
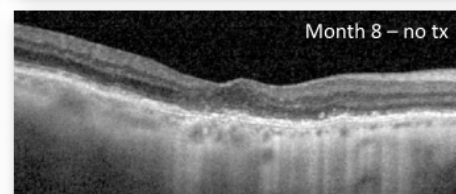
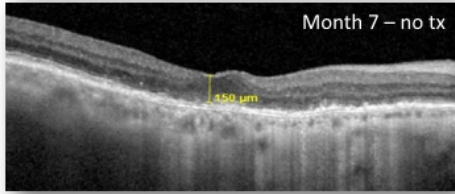
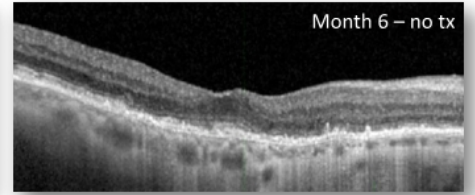
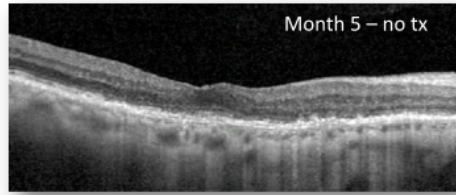
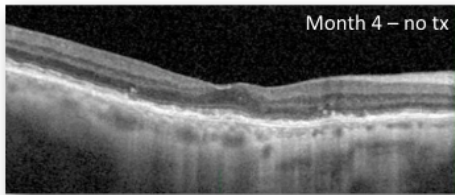
Screening visit prior to treatment

Screening Visit: 6 anti-VEGF injections prior to enrollment



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

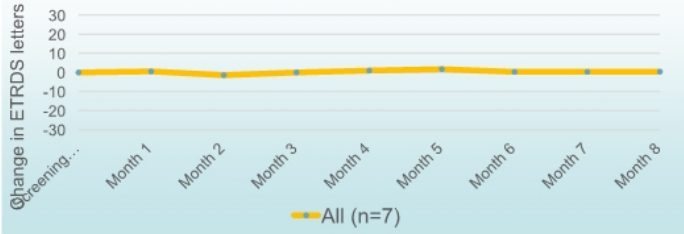
Low dose cohort (EYP-1901 440 μ g)



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

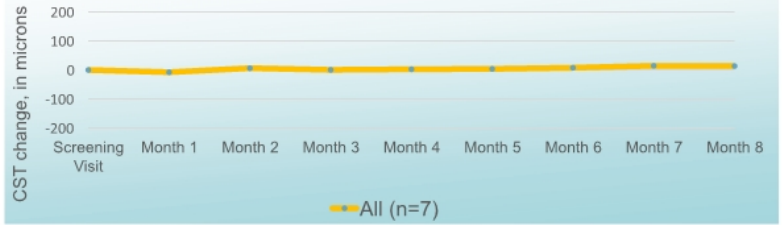
Average change in BCVA from screening visit – N = 7



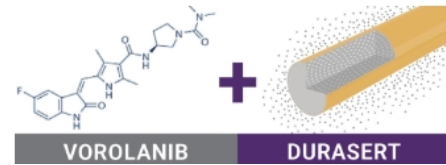
BCVA: best corrected visual acuity

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

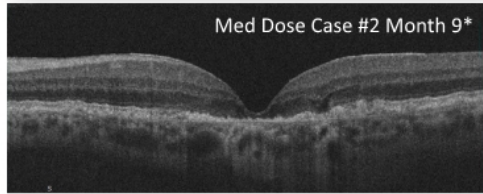
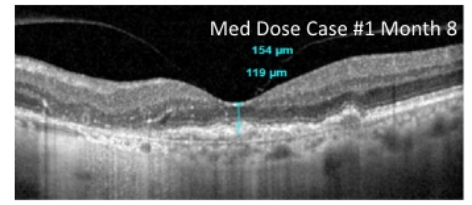
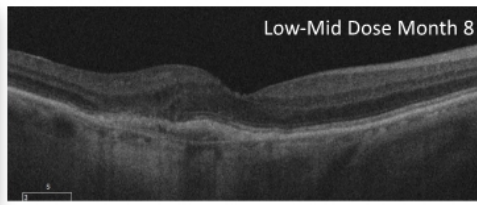
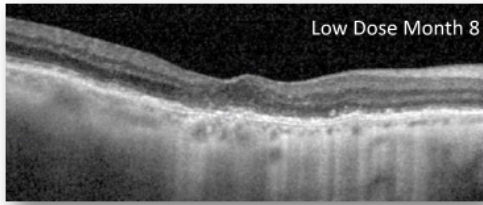
Average change in CST from screening visit – N = 7



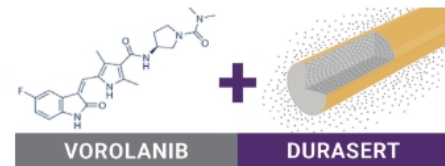
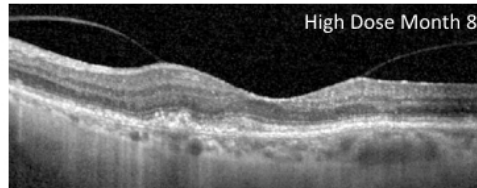
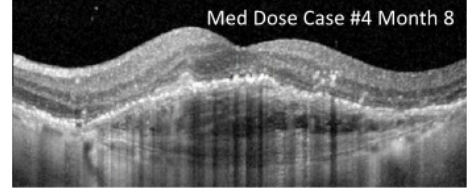
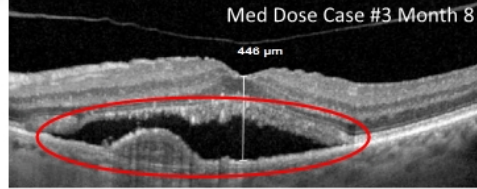
Interim data – monitored through 6 months



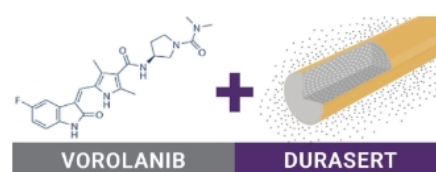
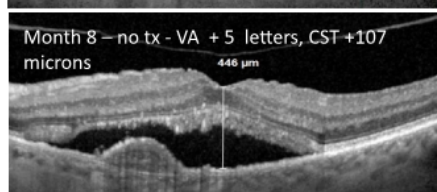
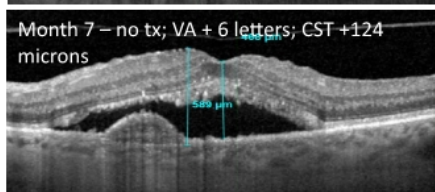
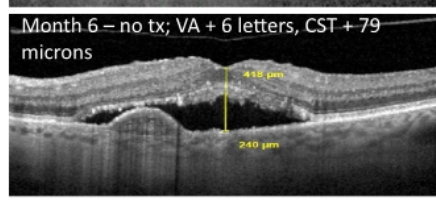
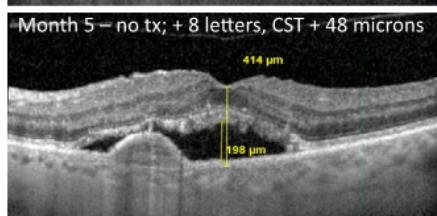
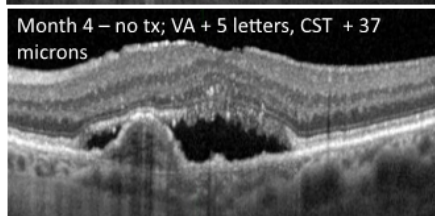
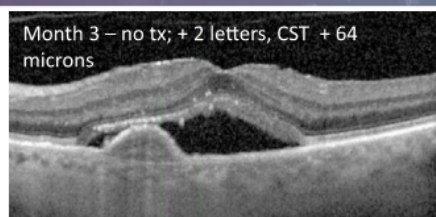
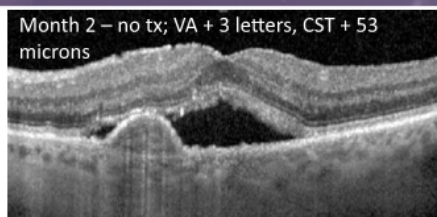
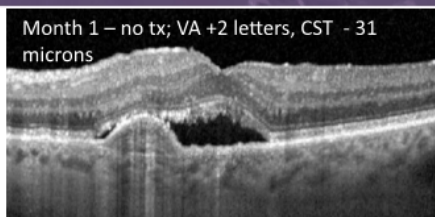
Longevity of Efficacy – At 8 months post EYP-1901, Six of Seven Unsupplemented Eyes Remain Dry



*Month 8 = missed visit

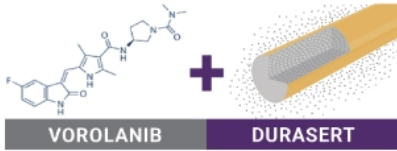


Unsupplemented Medium Dose Eye with Sub-retinal Fluid *SRF Fluctuates while VA Improved*



Next Steps for EYP-1901

EYP-1901



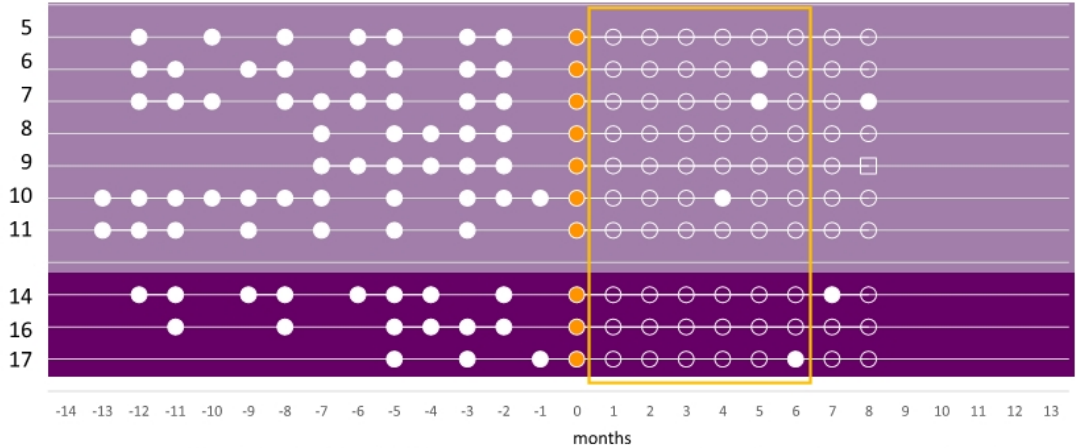
Three Phase 2 Trials Planned

- 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

SoC (Anti-VEGF) + EYP1901



Reduction in Treatment Burden of 89 % overall at 8 mos

Mid dose (n=7)
- 91%

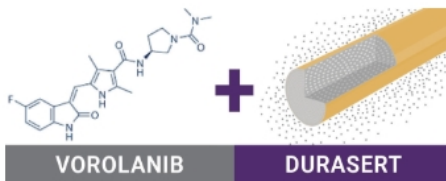
High dose (n=3)
- 85%

● Anti-VEGF ○ No supplemental injection given □ Missed visit

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



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