UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): July 27, 2023

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-51122**	**26-2774444**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

480 Pleasant Street	
Watertown, Massachusetts	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 926-5000

(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:

☐ Written communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications 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 Global Market

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

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 July 27, 2023, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing its reporting of interim masked safety data and patient baseline characteristics for the DAVIO 2 Clinical Trial. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

On the same date, the Company presented this information at the OIS Retina Innovation Summit in Seattle, Washington. A copy of the presentation is attached hereto as Exhibit 99.2 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of EyePoint Pharmaceuticals, Inc. dated July 27, 2023
99.2	EYP 1901 Phase 2 Davio Study Interim Results Presentation of EyePoint Pharmaceuticals, Inc. dated July 27, 2023
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: July 27, 2023

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

Exhibit 99.1

EyePoint Pharmaceuticals Presents Interim Masked Safety Data and Patient Baseline Characteristics for DAVIO 2 Clinical Trial at OIS Retina Innovation Summit

- *Interim safety data from the Phase 2 DAVIO 2 trial continues to demonstrate EYP-1901 is well tolerated with no reported drug-related ocular or systemic SAEs -*

- *Patient demographics demonstrate the Phase 2 DAVIO 2 population has a better baseline BCVA and decreased CST compared to the Phase 1 DAVIO trial cohort at trial start-*

- Phase 2 DAVIO 2 clinical trial remains on track to report topline data in December 2023 -

WATERTOWN, Mass., July 27, 2023 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced interim masked safety data and baseline patient demographics from its Phase 2 DAVIO 2 clinical trial of EYP-1901, a potential sustained delivery maintenance treatment for wet age-related macular degeneration (wet AMD). These data are being presented today at the OIS Retina Innovation Summit in Seattle, WA by Nancy Lurker, Executive Vice-Chair of EyePoint Pharmaceuticals.

“EYP-1901 continues to demonstrate an excellent safety profile in the Phase 2 DAVIO 2 trial with no reported drug-related ocular serious adverse events (SAEs) and no reported drug-related systemic SAEs in the 160 enrolled patients as of July 1, 2023,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. “Safety is paramount for both patients and physicians in the development of ophthalmic treatments, and these data support EYP-1901’s continued track record of safety in humans. We are developing EYP-1901 as a sustained delivery therapeutic option to maintain vision in a majority of wet AMD patients for up to six-months or longer, while also reducing the treatment burden of frequent injections and improving treatment compliance. Additionally, we are also pleased to present the Phase 2 DAVIO 2 patient baseline characteristics, demonstrating DAVIO 2 patients had better starting visual acuity and less central subfield thickness (CST) than the Phase 1 DAVIO cohort. We look forward to sharing our topline results from the DAVIO 2 trial in December of this year.”

A masked safety summary as of July 1, 2023 found that there have been no reported drug-related ocular SAEs and no reported drug-related systemic SAEs in the DAVIO 2 trial. There were two ocular SAEs unrelated to EYP-1901 in the trial:

- Retinal detachment in a study eye detected at week 1 (one week post initial aflibercept injection, prior to EYP-1901 injection)
- Retinal hemorrhage in a non-study fellow eye

EyePoint also presented the Phase 2 DAVIO 2 trial screening characteristics and provided a comparison to baseline demographics of the Phase 1 DAVIO patients. Interim baseline data on patients in the Phase 2 DAVIO 2 trial as of July 1, 2023 reveal that patients feature a mean best corrected visual acuity (BCVA) of 74 letters, compared with a mean BCVA of 69 letters in the Phase 1 DAVIO trial. Mean CST in the Phase 2 DAVIO 2 trial was 265 µm, compared to 299 µm in the Phase 1 DAVIO trial. Mean age of patients in the Phase 2 DAVIO 2 trial is 76 years old, compared to 77.4 years old in the Phase 1 DAVIO trial.

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with previously treated wet AMD. All enrolled patients had been previously treated with standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg) or an aflibercept control. EYP-1901 is delivered with a single intravitreal injection in the physician's office, similar to current FDA approved anti-VEGF treatments. The primary efficacy endpoint of the DAVIO 2 trial is change in BCVA compared to the aflibercept control, six-months after the EYP-1901 injection. Secondary efficacy endpoints include change in CST as measured by optical coherence tomography (OCT), number of eyes that remain free of supplemental anti-VEGF injections, number of aflibercept injections in each group, and safety. More information about the trial is available at clinicaltrials.gov (identifier: NCT05381948).

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment for retinal disease combining a bioerodible formulation of EyePoint's proprietary Durasert® delivery technology (Durasert E™) with vorolanib, a tyrosine kinase inhibitor. Positive safety and efficacy data from the Phase 1 DAVIO clinical trial of EYP-1901 in wet AMD showed a positive safety profile with stable visual acuity and OCT. Further, the data demonstrated an impressive treatment burden reduction of 75% at six months and 73% at the 12-month visit following a single dose of EYP-1901. Phase 2 trials are fully enrolled in wet AMD and non-proliferative diabetic retinopathy, and a diabetic macular edema trial is planned for initiation in Q1 2024. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology for sustained intraocular drug delivery including EYP-1901, an investigational sustained delivery intravitreal anti-VEGF treatment currently in Phase 2 clinical trials. The proven Durasert® drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. For more information visit www.eyepointpharma.com.

EYEPOINT SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the sufficiency of our existing cash resources into 2025; our plans and any other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments, including statements containing the words “will,” “potential,” “could,” “can,” “believe,” “intends,” “continue,” “plans,” “expects,” “anticipates,” “estimates,” “may,” other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint’s actual results to be materially different than those expressed in or implied by EyePoint’s forward-looking statements. For EyePoint, this includes uncertainties regarding our ability to realize the anticipated benefits of the 2023 sale of YUTIQ® to Alimera Sciences including our potential to receive additional payments from Alimera pursuant to the our agreements with Alimera; our ability to manufacture YUTIQ in sufficient quantities pursuant to our commercial supply agreements with Alimera and Ocumension Therapeutics; the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration, non-proliferative diabetic

retinopathy and diabetic macular edema; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the success of current and future license agreements, including our agreements with Alimera, Ocumension, Equinox Science and Betta Pharmaceuticals; termination or breach of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of competition; market acceptance of our products, including our out-licensed products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; the extent to which COVID-19 impacts our business and the medical community; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; the sufficiency of the Company's cash resources and need for additional financing; 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. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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Exhibit 99.2

Spotlight on Drug Delivery

Nancy Lurker, Executive Vice Chair, Board of Directors | OIS | July 27, 2023

EYEPOINT PHARMACEUTICALS

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 potential to receive future payments from Alimera pursuant to our May 2023 sale and license agreement with Alimera; the sufficiency of our existing cash resources into 2025; our expectations regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration, non-proliferative diabetic retinopathy and diabetic macular edema; 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; our ability to access needed capital; our ability to successfully manufacture sufficient quantities of YUTIQ® pursuant to our supply agreements with Alimera and Ocumension Therapeutics; the success of current and future license agreements, including our agreements with Alimera, Ocumension Therapeutics, Equinox Science and Betta Pharmaceuticals; termination or breach of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of guidelines, recommendations and studies; protection of our 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; the extent to which COVID-19 impacts our business and the medical community; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; 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.

COMPANY OVERVIEW

Committed to developing therapeutics to improve the lives of patients with serious eye disorders

Pipeline represents multi billion-dollar opportunity

- **EYP-1901** –bioerodible intravitreal (IVT) insert of patented vorolanib tyrosine kinase inhibitor (TKI) for retinal disease
  - Topline Phase 2 data in **wet AMD** anticipated in Dec 2023
  - Topline Phase 2 data in **NPDR** anticipated in 2Q 2024

Durasert® - proven IVT drug delivery technology

- Routine in-office IVT injection
- Able to deliver up to 3 inserts with single injection
- Safely administered to ~80,000 patient eyes across four FDA approved products with non erodible Durasert

Strong Balance Sheet

- ~$142M of cash and investments on June 30, 2023
- No debt – retired May 2023
- Cash runway into 2025

EyePoint Pharmaceuticals

EYP-1901

PHASE 1 DAVIO CLINICAL TRIAL RESULTS

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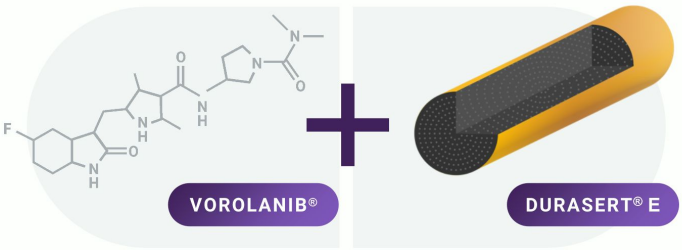
EYP-1901 Phase 1 DAVIO Clinical Trial Met All Objectives

FAVORABLE SAFETY PROFILE

- No ocular SAEs reported
- No drug-related systemic SAEs reported
- Ocular AEs – majority are mild and expected

POSITIVE EFFICACY & DURABILITY

- Stabilization of mean BCVA and OCT throughout 6 months was achieved
- 53% up to 6-months with no anti-VEGF supplemental injection
- 75% reduction in treatment burden at 6-months



SIX MONTHS MEDIAN TIME
TO SUPPLEMENTAL ANTI-VEGF INJECTION

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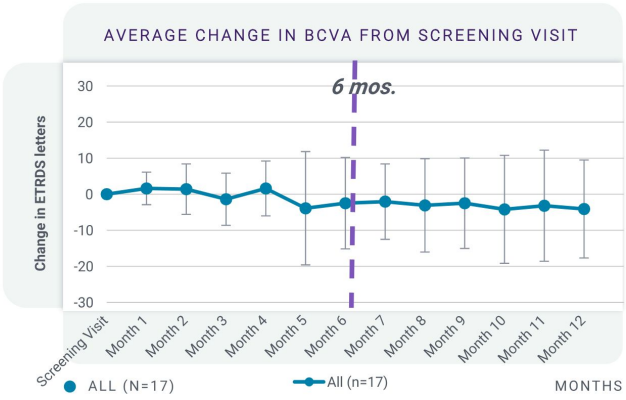
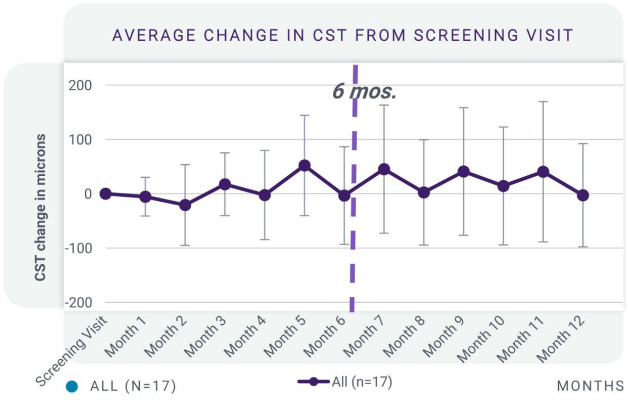
BCVA and CST Stable At 6 And 12 Months After Single Treatment Of EYP-1901 In The DAVIO Clinical Trial

Parameter	6 Months	12 Months
BCVA	−2.5	−4.1
CST	−3.4	−2.8





BCVA: best corrected visual acuity

OCT: optical coherence tomography;
CST: central subfield thickness

Error bars represent the standard deviation.

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EYP-1901

WET AMD PHASE 2 CLINICAL TRIAL - DAVIO 2

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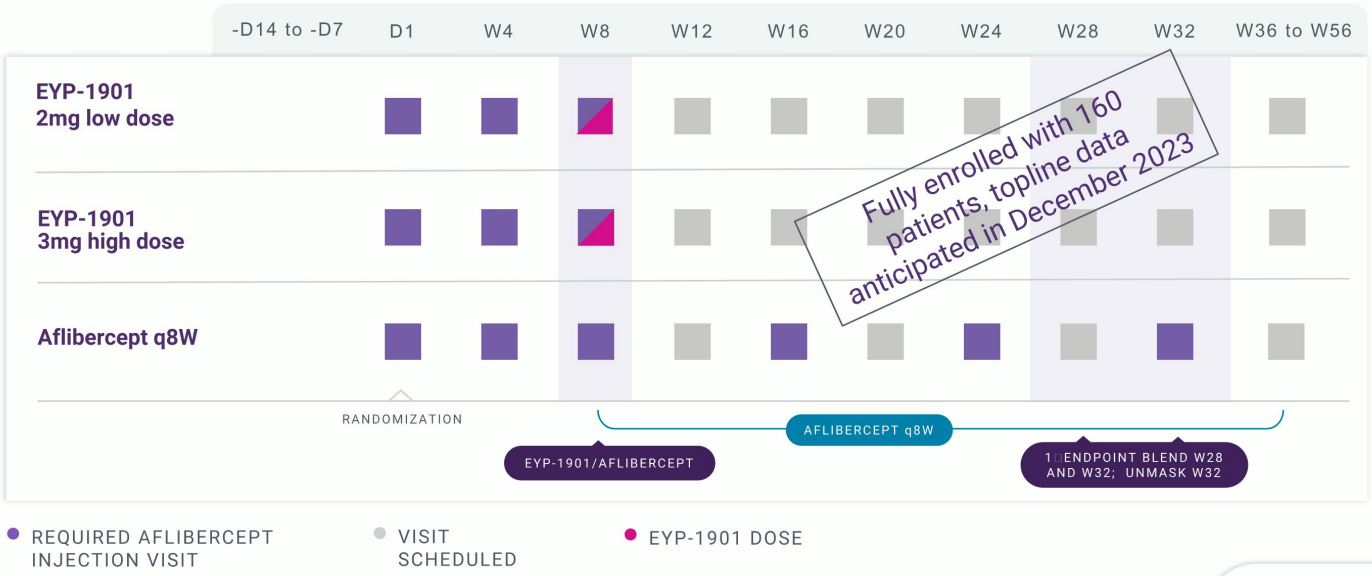
EYP-1901 Phase 2 DAVIO 2 Clinical Trial Is Randomized, Double-Masked, Aflibercept Controlled With A Single EYP-1901 Treatment At Two Doses



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Ph 1 DAVIO and Ph 2 DAVIO 2 Study Demographics

Phase 1 DAVIO Baseline Characteristics (N = 17)	
Mean age, y (range)	77.4 (67-94)
Female, %	76%
Mean BCVA, ETDRS letters (range)	69 (38-85)
Mean CST, µm (range)	299 (204-441)

Phase 2 DAVIO 2 Baseline Characteristics (N = 160)	
Mean age, y (range)	76 (52-93)
Female, %	62%
Mean BCVA, ETDRS letters (range)	74 (41-85)
Mean CST, µm (range)	265 (178-400)

**DAVIO 2 unmonitored data cut as of 01Jul2023

AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; VEGF, vascular endothelial growth factor.

Masked Safety Summary As Of July 1, 2023 Data-Cut Off

Key findings:

- No drug-related ocular SAEs
- No drug-related systemic SAEs
- 2 ocular SAEs:
  - Retinal detachment in a study eye detected at week 1 (one week post initial aflibercept injection, prior to EYP-1901 injection)
  - Retinal hemorrhage in a non-study fellow eye

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EYP-1901

PHASE 1 DAVIO CLINICAL TRIAL SUBGROUP ANALYSIS – NINE SUBJECTS WITH NO EXCESS FLUID AT SCREENING

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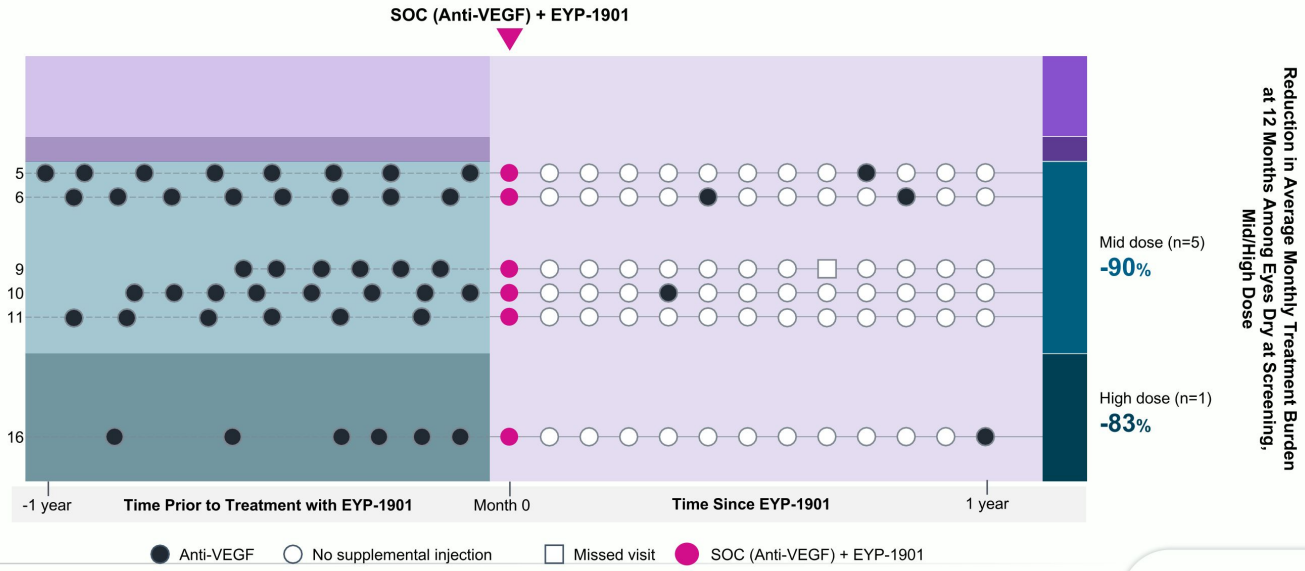
Subgroup Analysis: 89% Reduction In Treatment Burden At 12 Months Among Mid/High Dose Subjects With No Excess Fluid At Screening (n=6)

SOC Anti-VEGF Injections Before and After Treatment



SOC, standard of care; VEGF, vascular endothelial growth factor.

DAVIO Final 12-Months Data

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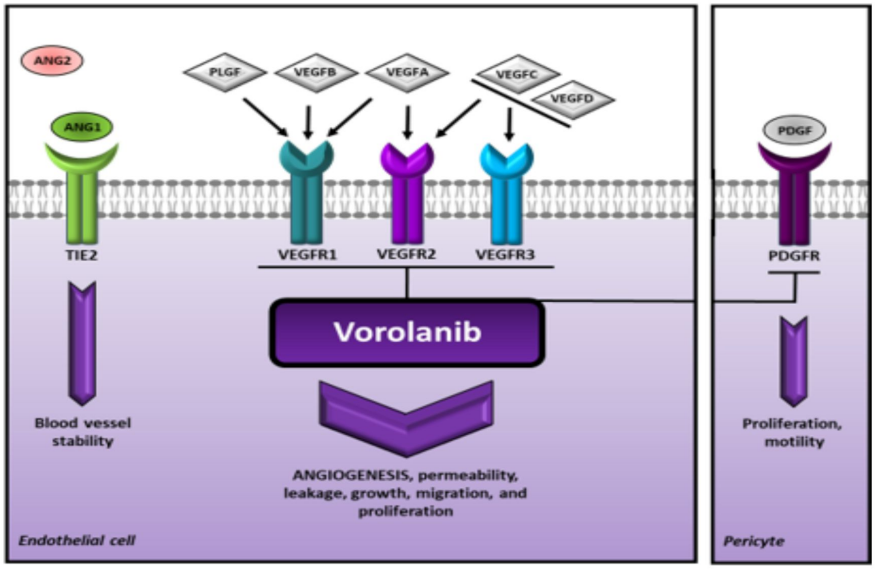
Vorolanib: A Potent Pan-VEGF Receptor Inhibitor

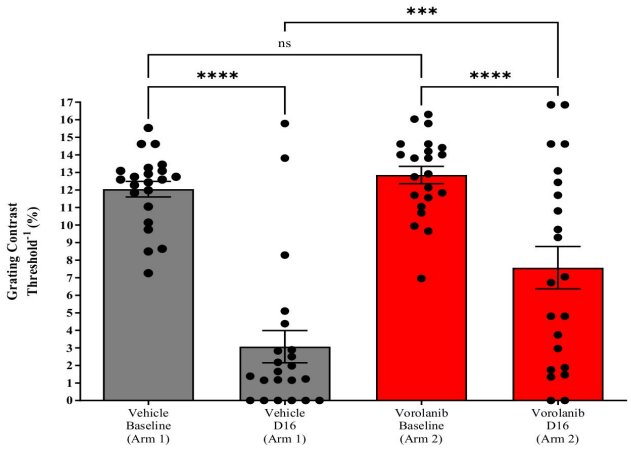
- Vorolanib inhibits pathways with key roles in angiogenesis:
  - **Potent and selective pan–VEGF receptor** inhibitor
- Acts **intracellularly** and inhibits proangiogenic signaling



ANG, angiopoietin; PDGF(R), platelet-derived growth factor (receptor); PLGF, placental growth factor; TIE2,tyrosine-protein kinase receptor TIE-2; VEGF(R), vascular endothelial growth factor (receptor).

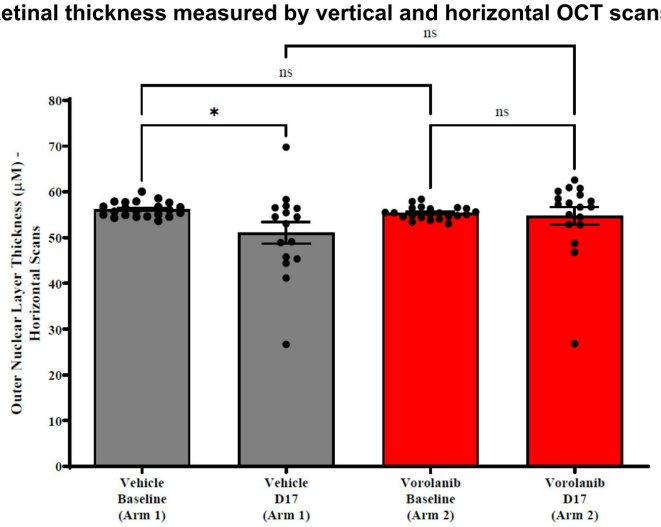
Vorolanib Demonstrated The Ability To Provide Retinal Neuroprotection In Validated Mouse Model

Mean Change in Contrast Vision at Day 16 from Baseline in Animals Treated with Vorolanib vs Vehicle Control



34% reduction in loss of contrast vision vs. control

Retinal thickness measured by vertical and horizontal OCT scans



<1% Overall loss of ONL vs control

ONL: Outer Nuclear Layer

Data presented at ARVO 2023

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EYP-1901

NON-PROLIFERATIVE DIABETIC RETINOPATHY - PHASE 2 CLINICAL TRIAL (PAVIA)

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EYP-1901 Phase 2 PAVIA Clinical Trial Is Randomized Double-Masked, Single Injection With Sham Control As A 9-Month Treatment In NPDR

- Moderate to severe NPDR patients enrolled
- Primary endpoint is ≥**2 letter DRSS improvement level at week 36**
- Secondary endpoints:
  - Reduction in vision-threatening complications
  - DME occurrence and/or proliferative disease
  - Retinal ischemia
  - Safety

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Pipeline Represents Multibillion Dollar Opportunity

Program	Indication	Discovery	Pre-Clin	Phase 1	Phase 2	Phase 3	Next Milestone
EYP-1901 – (vorolanib in Durasert E™)	**wet AMD**	*single dose 6-month maintenance therapy*					Topline data in December 2023
	NPDR	*single dose 9-month treatment*					Topline data in Q2 2024
	DME	*single dose 6-month treatment*					Trial Initiation in Q1 2024
Complement programs	**Dry AMD GA**						Potential product candidate in 2024

trial underway
trial planned
discovery

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Continued Execution And Well Funded Through Key EYP-1901 Milestones

	EYP-1901	
✓	DAVIO 1 trial complete	2Q 2022
✓	DAVIO 2 trial initiated	3Q 2022
✓	PAVIA trial initiated	3Q 2022
✓	DAVIO 2 enrollment complete	1Q 2023
✓	PAVIA enrollment complete	2Q 2023
☐	**DAVIO 2 topline data**	**December 2023**
☐	**DME Trial initiation**	**1Q 2024**
☐	**PAVIA topline data**	**2Q 2024**

	Corporate	
✓	RallyBio complement inhibitor (C5) collaboration	1Q 2023
✓	YUTIQ transacted for $82.5M plus royalties	2Q 2023
✓	Debt retired and cash runway extended into 2025	2Q 2023

EyePoint Pharmaceuticals

Nancy Lurker | OIS | July 2023

Thank you!

Spotlight on Drug Delivery

EyePoint Pharmaceuticals