# 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): December 04, 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 December 4, 2023, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive topline data for its lead product candidate, EYP-1901, from the Company's Phase 2 DAVIO 2 clinical trial in wet age-related macular degeneration. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Additionally, on December 4, 2023, the Company posted an updated investor presentation on its website at www.eyepointpharma.com. A copy of the presentation is filed herewith as Exhibit 99.2 and is 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 December 4, 2023 |
| 99.2 | Investor Presentation of EyePoint Pharmaceuticals, Inc. dated December 4, 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: December 4, 2023

By: /s/ George O. Elston
George O. Elston
Executive Vice President and Chief Financial Officer

**Exhibit 99.1**

**EyePoint Pharmaceuticals Announces Positive Topline Data from the Phase 2 DAVIO 2 Trial of EYP-1901 in Wet AMD Achieving All Primary and Secondary Endpoints**

- *Both EYP-1901 cohorts demonstrated a statistically non-inferior change in BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2 mg and 3 mg dose at blended six-month endpoint –*

- *Positive safety profile continues with no EYP-1901-related ocular or systemic SAEs –*

- *Key secondary endpoints were achieved with both EYP-1901 doses. These include an over 80% reduction in treatment burden, with nearly two-thirds of eyes supplement-free up to six-months –*

- *Strong anatomical control in both EYP-1901 cohorts documented by optical coherence tomography (OCT) –*

- *Conference call to discuss the results to be held today, December 4, 2023 at 8:00 a.m. ET –*

WATERTOWN, Mass., December 4, 2023 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious retinal diseases, today announced positive topline results of its Phase 2 DAVIO 2 trial of EYP-1901, an investigational sustained delivery maintenance treatment for wet age-related macular degeneration (wet AMD) combining vorolanib, a selective tyrosine kinase inhibitor with bioerodible Durasert E™. The clinical trial met its primary endpoint with both EYP-1901 doses demonstrating statistical non-inferiority change in best corrected visual acuity (BCVA) compared to aflibercept control and a favorable safety profile with no EYP-1901-related ocular or systemic serious adverse events (SAEs). The trial also achieved key secondary endpoints with both EYP-1901 doses, including an over 80% reduction in treatment burden, nearly two-thirds of eyes supplement-free up to six months and over 80% receiving only zero or one supplement up to six-months. Additionally, there was strong anatomical control with both EYP-1901 cohorts as measured by optical coherence tomography (OCT).

“We are incredibly pleased by these highly positive Phase 2 results which underscore EYP-1901’s potential as a paradigm-altering maintenance treatment for patients with wet AMD, with a positive safety profile. Since EYP-1901 achieved statistical non-inferiority to the aflibercept control in this trial there is potential for meaningfully lower sized and lower cost pivotal Phase 3 trials.” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. “I would like to thank the patients and the investigators who participated in the DAVIO 2 trial as well as our employees who helped advance us to this important milestone.”

Dr. Duker continued, “the DAVIO 2 clinical trial was designed to support the initiation of Phase 3 clinical trials based on feedback received from the U.S. Food and Drug Administration (FDA) at a Type C meeting last year. The 32-week topline DAVIO 2 data strongly supports our planned Phase 3 non-inferiority design, consistent with the FDA’s recent guidance for wet AMD clinical trials. We look forward to continuing our dialogue regarding our Phase 3 plans with the FDA as we prepare to initiate our first pivotal trial for wet AMD in the second half of 2024.”

“These highly positive Phase 2 results are the result of years of hard work by the dedicated EyePoint team coupled with our proven Durasert technology which continues to demonstrate the benefit of zero order kinetics drug delivery. I look forward to initiation of Phase 3 and potentially bringing this innovative and much needed new drug to market for patients suffering from these blinding eye diseases. “ said Nancy Lurker, Executive Vice Chair of EyePoint Pharmaceuticals. “I want to congratulate the EyePoint team on the continued execution of this program.”

DAVIO 2 topline interim results include:

- Both EYP-1901 doses (2mg and 3mg) achieved all primary and secondary endpoints.
- Statistical non-inferiority in change in BCVA (at a confidence interval of 95%) compared to aflibercept control, at weeks 28 and weeks 32 combined. The 2mg and 3mg doses were only -0.3 and -0.4 letters different, respectively, versus on-label aflibercept. The lower limit of the non-inferiority margin is defined as a -4.5 letters by the FDA with 5 letters representing one line on the eye chart.
- Continued positive safety and tolerability profile with no EYP-1901-related ocular or systemic SAEs.
- 89% and 85% reduction in treatment burden, respectively, for the 2mg and 3mg EYP-1901 doses.
- 65% and 64% of eyes were supplement free up to six-months, respectively, for the 2mg and 3mg doses of EYP-1901.
- Both EYP-1901 doses demonstrated strong anatomic control with OCT difference below 10 microns at week 32 compared to the aflibercept control.
- Patient discontinuation up to week 32 was low at 4%.

“Wet AMD is a prevalent and progressive lifetime disease. With frequent treatment, patients can maintain their visual acuity, but the unfortunate reality is that many patients end up undertreated due to the burden of dosing of the currently available, short-acting anti-VEGF therapies," said Carl Regillo, M.D., Chief of Retina Service at Wills Eye Hospital. "I am very encouraged by the data generated from both the Phase 1 DAVIO and Phase 2 DAVIO 2 trials with the latter showing essentially no difference in visual outcome at the blended six-month endpoint from a single injection of EYP-1901 compared to on-label, bimonthly aflibercept injections. Based on the meaningful reduction in treatment burden and supplement-free rates observed, along with the consistently favorable safety profile, I believe that EYP-1901 could be a paradigm shift in how patients with wet AMD are treated.”

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of EYP-1901 in previously treated patients with wet AMD. Originally designed to enroll 144 patients, the trial enrolled 160 patients in total due to strong investigator and patient interest. All enrolled patients were previously treated with a 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 non-inferiority efficacy endpoint is change in BCVA compared to the aflibercept control, approximately six-months after the EYP-1901 injection. Secondary endpoints include safety, change in CST as measured by OCT, the number of eyes that remain free of supplemental anti-VEGF injections, and number of aflibercept injections in each group. More information about the trial is available at clinicaltrials.gov (identifier: NCT05381948).

EyePoint plans to present the DAVIO 2 dataset at Angiogenesis, Exudation, and Degeneration 2024 in February.

The Company remains on track to reach additional clinical milestones with EYP-1901 with the initiation of the Phase 2 VERONA trial in diabetic macular edema (DME) anticipated in the first quarter of 2024 and the readout of topline data from the Phase 2 PAVIA trial in non-proliferative diabetic retinopathy (NPDR) anticipated in the second quarter of 2024.

**Conference Call and Webcast Information**

EyePoint will host a conference call today, December 4, 2023 at 8:00 a.m. ET to discuss the results. To access the live conference call, please register at https://register.vevent.com/register/BI4c4d93355a394ea284131d7b537fd513. A live audio webcast of the event can be accessed via the Investors section of the Company website at www.eyepointpharma.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

**About Wet AMD**

Age-related Macular Degeneration (AMD) is a leading cause of irreversible blindness or vision loss in people over the age of 60. Wet AMD is an advanced form of the condition that develops when abnormal blood vessels grow into the macula, leaking blood or fluid that leads to scarring of the macula and potentially rapid and severe vision loss. Wet AMD is a lifelong disease that requires continuous treatment so that patients may maintain visual function. Although multiple treatments are now available, challenges still exist as the current standard-of-care is dosed on average every two months in the United States under a treat-and-extend protocol, and these large molecule anti-VEGF treatments only target one pathology of the disease. This lifetime of frequent treatment represents a tremendous burden for patients, physicians, and the health care system, potentially leading to patient noncompliance and further vision loss.

**About EYP-1901**

EYP-1901 is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. EYP-1901 delivers vorolanib, a selective and patent-protected tyrosine kinase inhibitor (TKI) formulated in a solid bioerodible insert using Eyepoint’s proprietary sustained-release Durasert E™ technology. Vorolanib brings a new mechanistic approach to the treatment of VEGF-mediated retinal diseases as a pan-VEGF receptor blocker, blocking all VEGF isoforms. Vorolanib features reduced off-target binding and at clinically relevant doses does not inhibit Tie-2, a critical pathway associated with vascular stability, which may result in an improved efficacy. Further, in an in-vivo model of retinal detachment, vorolanib demonstrated neuroprotection, and potential antifibrotic benefits. EYP-1901 is shipped and stored at ambient temperature and is administered with a single intravitreal injection in the physician's office. EYP-1901 is immediately bioavailable, featuring an initial burst of drug, followed by near constant zero-order kinetic release for approximately nine months.

Positive data from both the Phase 1 DAVIO and Phase 2 DAVIO 2 clinical trials of EYP-1901 in wet AMD demonstrated clinically meaningful efficacy data with stable visual acuity and OCT, and a favorable safety profile. Further, the recent DAVIO 2 data demonstrated an impressive treatment burden reduction of over 85% at six months, and over 80% of patients remained supplement-free or only received one supplemental anti-VEGF injection up to 6 months. The data from the DAVIO 2 clinical trial supports the advancement of the wet AMD program to Phase 3 pivotal trials which are anticipated to initiate in the second half of 2024.

EYP-1901 is also being studied in non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME). The Phase 2 PAVIA trial in NPDR is fully enrolled with topline data anticipated in the second quarter of 2024. The Phase 2 VERONA trial in DME is planned to initiate in the first quarter of 2024.

**About EyePoint Pharmaceuticals**

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical-stage company committed to developing and commercializing therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology for sustained intraocular drug delivery. The company's lead product candidate, EYP-1901, is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor (TKI) with Durasert E™. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases. Additional pipeline programs include EYP-2301, a promising Tie-2 activator, razuprotafib, f/k/a AKB-9778, formulated in Durasert E™ to potentially improve outcomes in wet AMD and diabetic eye disease. The proven Durasert® drug delivery platform has been safely administered to over thousands of patient 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 use of proceeds for the offering and other statements identified by words such as "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 the timing and clinical development of our product candidates, including EYP-1901 and EYP-2301; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration (wet AMD) and non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME); the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals including potential U.S. Food and Drug Administration (FDA) regulatory approval of EYP-1901 and EYP-2301; the success of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; the success of Durasert® as a drug delivery platform in FDA approved products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; 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.

**Investors:**
Christina Tartaglia
Stern IR
Direct: 212-698-8700
christina.tartaglia@sternir.com

**Media Contact:**
Amy Phillips
Green Room Communications
Direct: 412-327-9499
aphillips@greenroompr.com

Exhibit 99.2

# EYP-1901 in wet AMD DAVIO 2 Phase 2 Clinical Trial Topline Data

December 4, 2023

# 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 the sufficiency of our existing cash resources into 2025; our expectations regarding the timing and clinical development of our product candidates, including EYP-1901 and EYP-2301; 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; 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 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.




EYEPOINT PHARMACEUTICALS

Committed to developing therapeutics to improve the lives of patients with serious retinal diseases

## Pipeline represents potentially substantial opportunities using our bioerodible Durasert E™ IVT delivery technology

- **EYP-1901** – vorolanib, a selective and patented TKI
  - Positive topline Phase 2 data in **wet AMD**
  - Phase 3 trials in **wet AMD** planned to initiate in 2H 2024
  - Topline Phase 2 data in **NPDR** anticipated in Q2 2024
  - Phase 2 trial in **DME** planned to commence in Q1 2024
- **EYP-2301 –** *razuprotafib,* a patented TIE-2 agonist for serious retinal diseases

## Durasert® - proven, safe IVT drug delivery technology

- Routine in-office IVT injection
- Bioerodible and non-erodible formulations
- Safely administered to thousands of patient eyes across four FDA approved products with non-erodible formulations

## Strong Balance Sheet

- $136.0M of cash and investments on September 30, 2023
- Cash runway into 2025

IVT, intravitreal injection

# EYP-1901 (vorolanib in Durasert E) a potential treatment for wet AMD featuring sustained delivery for 6-months or longer

EyePoint Pharmaceuticals

# There is a Significant Need for More Durable Therapies in Wet AMD

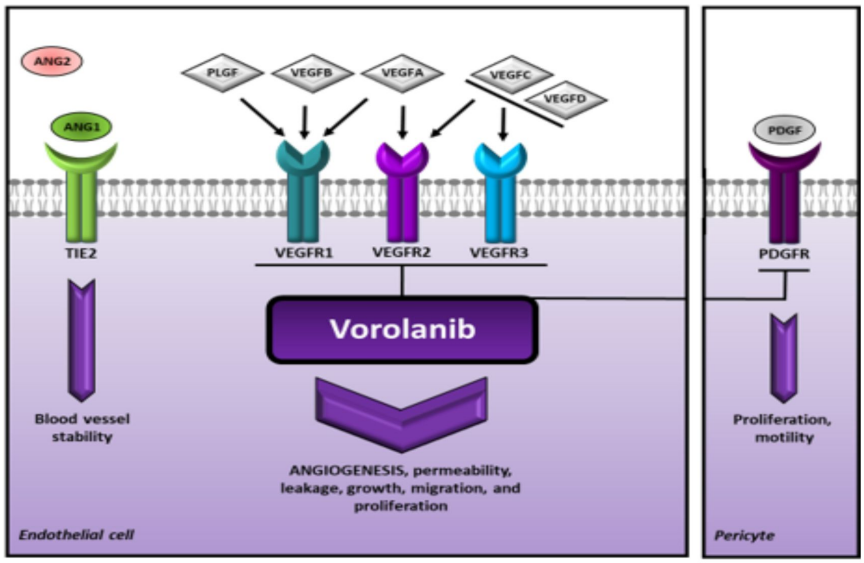
1. **Many patients with wet AMD are chronically undertreated**
   - >80% of Retina Specialists say undertreatment is due to patient noncompliance, scheduling limitations or provider preference for less frequent dosing[1]
2. **Current "treat and extend" protocol still places significant burden on physicians and patients**
   - Chronic disease treated with short acting anti-VEGF biologics
3. **A delay in care/missed visit can result in vision loss**
   - A delay in treatment of only 5.34 weeks resulted in vision loss[2]
4. **An aging population means significantly more injections in a patient's lifetime**
   - Current anti-VEGF treatments are dosed on average every two months in the United States[3]




1. 2022 PAT Survey; 2. American Academy of Ophthalmology, *The Effect of Delay in Care Among Patients Requiring Intravitreal Injections,* Welin Song, BS et al; 3. NIH *Current and Upcoming Anti-VEGF Therapies and Dosing Strategies for the treatment of neovascular AMD: a comparative review,* Saira Khanna et al, Dec. 2019

# Vorolanib Brings a Potential New MOA to the Treatment of VEGF-Mediated Retinal Diseases by Blocking all Isoforms of VEFG and PDGF

- Potent and selective pan–VEGF receptor inhibition
- Composition of matter patent into 2037
- Demonstrated neuroprotection in a validated retinal detachment animal model
- Blocks PDGF which may lead to antifibrotic benefit
- Reduced off-target binding and does not inhibit TIE-2 at clinically relevant doses




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

TECHNOLOGY

# DURASERT®

**Safe Sustained IVT Drug Delivery**

- Delivered by a single in-office IVT injection
- Continuous, stable release of drug
- Zero-order kinetics

**Durasert E™: bioerodible**

- Insert consists of drug embedded within a bioerodible matrix
- Designed to deplete drug load before matrix fully erodes

**Durasert®: non-erodible**

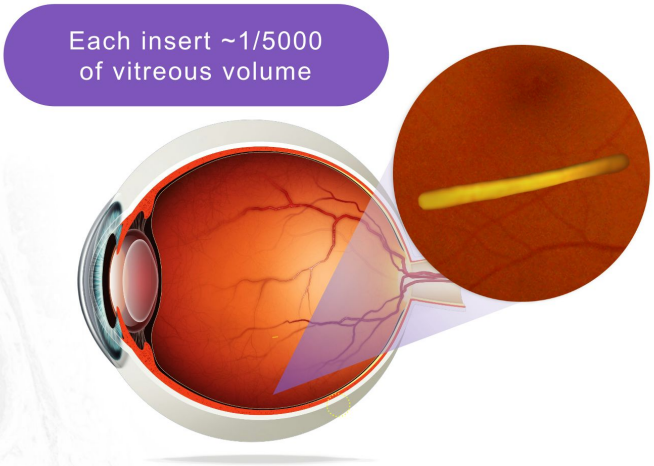
- Drug embedded within a bioerodible matrix coated with non-erodible polyimide shell:
  - YUTIQ®[1]
  - ILUVIEN®[1]
  - RETISERT®[2]
  - VITRASERT®[2]





1- licensed to Alimera; 2 – licensed to Bausch and Lomb

# EYP-1901: Receptor Binding Vorolanib In Bioerodible Durasert E™




- Delivered in the physician office via standard intravitreal injection technique
- Immediately bioavailable featuring an initial burst of drug followed by zero order kinetics release for ~9 months
- Positive safety and efficacy data in wet AMD from Phase 1 DAVIO clinical trial
- Continued positive safety data in ongoing Phase 2 clinical trials with all patients at least six months post injection
- Shipped and stored at ambient temperature




IVEGF – vascular endothelial growth factor: AMD – age related macular degeneration;

EyePoint Pharmaceuticals

# The DAVIO 2 Clinical Trial – Background

A non-inferiority trial evaluating two doses of EYP-1901 against an aflibercept control in wet AMD




**The DAVIO 2 clinical trial was designed to evaluate EYP-1901 in wet AMD and support Phase 3 clinical trials based on a Type C meeting with FDA**

**Design:** Multi-center, randomized, double-masked trial in patients with previously treated wet AMD

**Anti-VEGF supplement criteria:**

- 5 letter loss with 75 microns of new fluid
- Other criteria
  - 10 letter loss due to wet AMD
  - 100 microns new fluid x 2 visits
  - New retinal hemorrhage from wet AMD
  - Investigator discretion

**Primary outcome:** difference in mean change in BCVA from Day 1 to Week 28 and 32 (blended)

**Key secondary endpoints:** safety, reduction in treatment burden, percent of eyes supplement-free up to six months and anatomical results

EyePoint Pharmaceuticals

# DAVIO 2 Clinical Trial is Randomized, Double-Masked, Aflibercept Controlled* with a Single EYP-1901 Treatment at Two Doses


REQUIRED AFLIBERCEPT INJECTION VISIT

VISIT SCHEDULED

EYP-1901 DOSE

SHAM INJECTION FOR MASKING

*Aflibercept on-label control required by FDA

# DAVIO 2 Baseline Characteristics Well Balanced Across Arms

| | Aflibercept 2mg q8W (n=54) | EYP-1901 2mg (n=50) | EYP-1901 3mg (n=52) |
|---|---|---|---|
| Mean age, years (range) | 75.9 (52-93) | 76.4 (61-93) | 75.4 (56-89) |
| Female, % | 53.7% | 64.0% | 67.3% |
| Mean BCVA, ETDRS letters (range) | 73.4 (41-85) | 73.9 (52-84) | 74.9 (46-85) |
| Mean CST, µm (range) | 265.7 (178-348) | 267.0 (192-400) | 262.9 (186-345) |
| Median length of time for wet AMD diagnosis prior to screening, months (range) | 28.1 (2.4-273.6) | 24.2 (2.4-168.0) | 28.1 (2.4-145.2) |
| Mean # of injections normalized to 12 months prior to screening (range) | 9.5 (1.0-12.0) | 10.1 (2.0-13.0) | 10.0 (2.0-13.3) |




PRELIMINARY DATA – PENDING FINAL ANALYSIS

EYEPOINT PHARMACEUTICALS

# Phase 2 DAVIO 2 Clinical Trial Topline Results

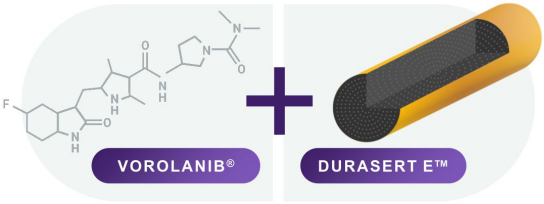
## A NON-INFERIORITY TRIAL VERSUS AN AFLIBERCEPT CONTROL

EyePoint Pharmaceuticals

# EYP-1901 Phase 2 DAVIO 2 Clinical Trial Met All Objectives

## MET PRIMARY ENDPOINT

- ✓ **Statistically non-inferior** change in BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2 mg and 3 mg dose
- ✓ **Continued favorable safety profile:**
  - No EYP-1901-related SAEs reported
  - Ocular AEs – majority are mild in severity and expected with mode of administration




## MET ALL SECONDARY ENDPOINTS

- ✓ **~80% reduction** in treatment burden at 6-months
- ✓ Nearly **two-thirds of eyes supplement-free** up to six-months
- ✓ **Strong anatomical control** in both EYP-1901 arms



PRELIMINARY DATA – PENDING FINAL ANALYSIS

# DAVIO 2 Achieved Primary Endpoint of Non-Inferiority Change in Visual Acuity in Both EYP-1901 Arms; Statistically and Numerically Non-Inferior to Control (95% CI)

| | EYP-1901 2mg | EYP-1901 3mg | Aflibercept 2mg q8W |
|---|---|---|---|
| Change in BCVA* vs. Baseline | + 1.0 letters | + 0.9 letters | + 1.3 letters |
| Difference vs. Aflibercept Control | **- 0.3 letters** | **- 0.4 letters** | NA |
| Statistics | NI (95% CI) | NI (95% CI) | NA |

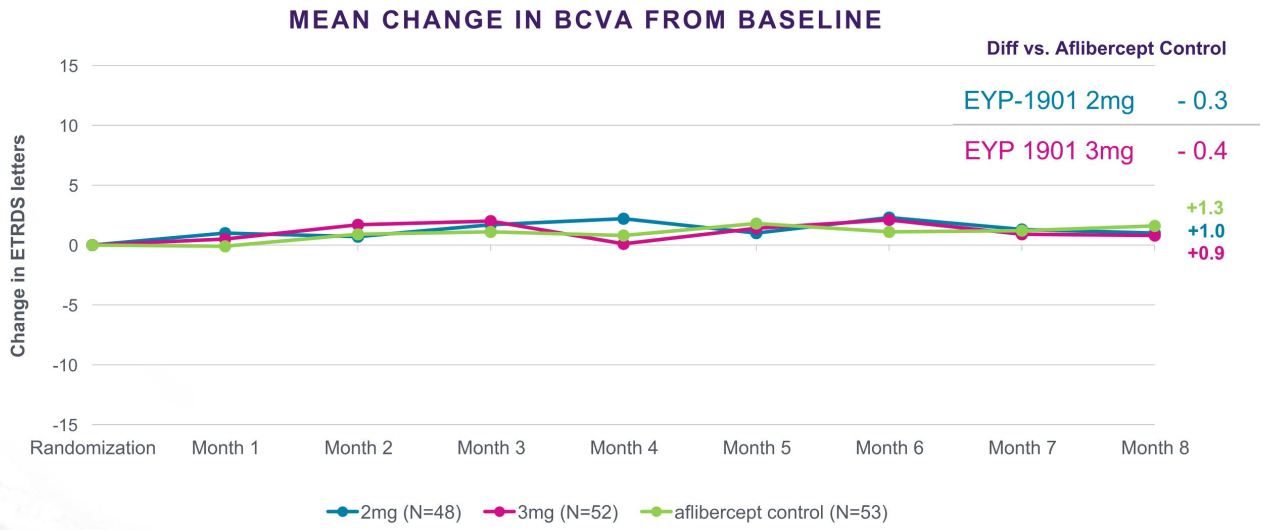
Non-inferiority Margin = - 4.5 letters per FDA guidance

*Blended week 28 and week 32
NI, Non-inferior; CI, Confidence Interval
PRELIMINARY DATA – PENDING FINAL ANALYSIS




EyePoint PHARMACEUTICALS

# EYP-1901 was Statistically Non-Inferior in Change in BCVA Compared to the Aflibercept Control (95% CI)




*Blended week 28 and week 32 change vs. baseline
CI, Confidence Interval
PRELIMINARY DATA – PENDING FINAL ANALYSIS

# EYP-1901 Demonstrated a Favorable Safety Profile in the Phase 2 DAVIO 2 Trial (Data Cut as of November 7, 2023)

- No reported EYP-1901-related ocular SAEs
  - Four ocular SAEs reported in a study eye – none deemed related to EYP-1901[1]
- No reported EYP-1901-related systemic SAEs
- AEs reported were generally mild and expected with IVT[2]
- No cases of:
  - Insert migration into the anterior chamber
  - Retinal occlusive vasculitis
- Low patient discontinuation rate of 4% up to week 32
  - No discontinuations were related to AEs or EYP-1901 treatment

1- As determined by investigator
2- Further details to be provided following completion of internal review
SAE, serious adverse event; AE, adverse event; IVT, intravitreal injection
PRELIMINARY DATA – PENDING FINAL ANALYSIS

# Clinically Meaningful Reduction in Treatment Burden Supports EYP-1901 as a Maintenance Treatment For Wet AMD

| | EYP-1901 2mg | EYP-1901 3mg |
|---|---|---|
| Mean number of injections week 8 through week 32 | 0.55 | 0.71 |
| Mean number of injections 6 months prior to screening* | 5.07 | 4.98 |
| **Reduction in treatment burden vs. 6 months prior (%)** | **89%** | **85%** |

*Normalized

PRELIMINARY DATA – PENDING FINAL ANALYSIS




EYEPOINT PHARMACEUTICALS

# EYP-1901 Demonstrated a Significant Reduction in Treatment Burden vs. the Aflibercept Control Arm

| | EYP-1901 2mg | EYP-1901 3mg | Aflibercept 2mg q8W |
|---|---|---|---|
| Mean number of injections week 8 through week 32 | 0.55 | 0.71 | 3.32 |
| **Reduction in treatment burden vs. aflibercept control (%)** | **83%** | **79%** | **NA** |




PRELIMINARY DATA – PENDING FINAL ANALYSIS.

EYEPOINT PHARMACEUTICALS

# EYP-1901 Demonstrated Clinically Meaningful Supplement-Free Rates

**PERCENT OF PATIENTS SUPPLEMENT-FREE UP TO SIX MONTHS AFTER ADMINISTRATION OF EYP-1901**

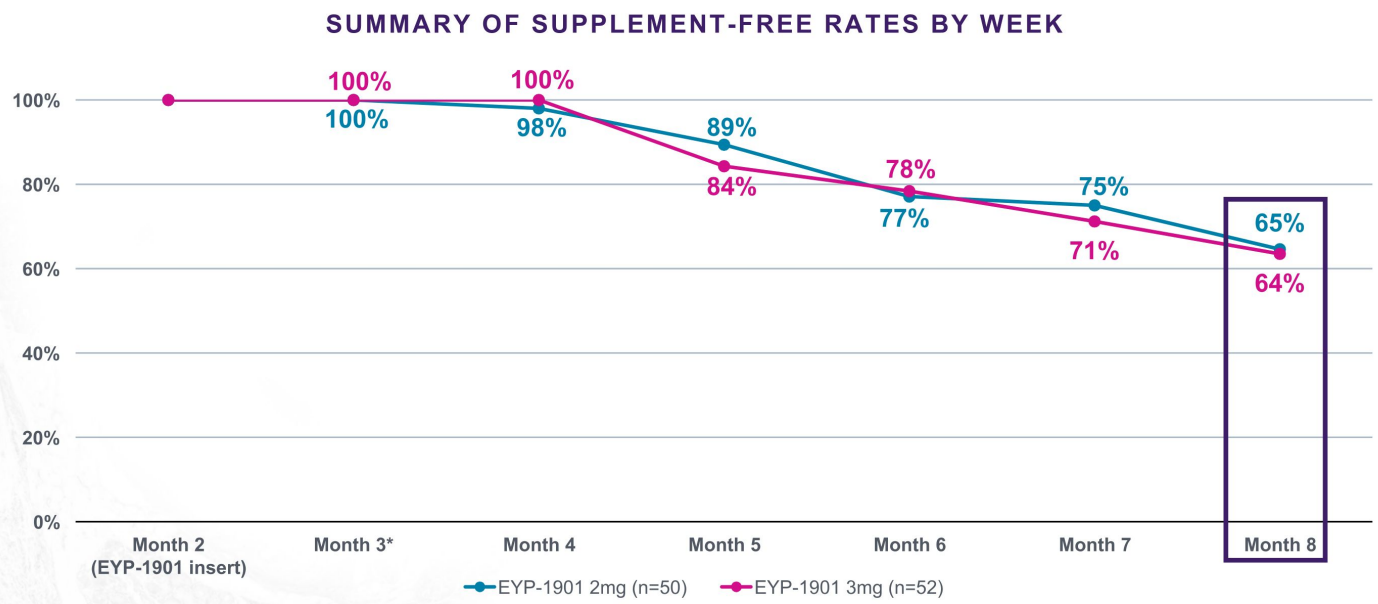
| | EYP-1901 2MG | EYP-1901 3mg |
|---|---|---|
| **Supplement-Free Rates** | **65%** | **64%** |




PRELIMINARY DATA – PENDING FINAL ANALYSIS

EYEPOINT PHARMACEUTICALS

# Nearly Two-Thirds of Eyes Treated with EYP-1901 were Supplement-Free up to Six Months After a Single Injection




*First visit patients are eligible to be rescued
PRELIMINARY DATA – PENDING FINAL ANALYSIS

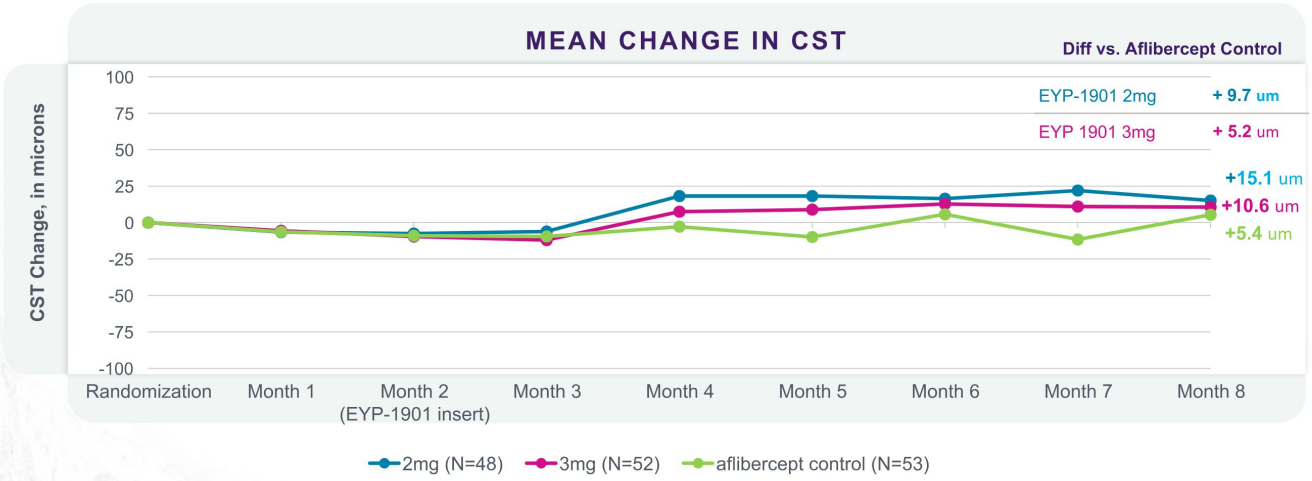
# Stable Anatomy via OCT in EYP-1901 Arms

| | EYP-1901 2mg | EYP-1901 3mg | Aflibercept 2mg q8W |
|---|---|---|---|
| Baseline CST (mean) | 262.9 | 267.0 | 265.7 |
| Change in OCT at Week 32 vs. Baseline | + 15.1 microns | + 10.6 microns | + 5.4 microns |
| **Difference vs. Aflibercept Control** | **+ 9.7 microns** | **+ 5.2 microns** | **NA** |



PRELIMINARY DATA – PENDING FINAL ANALYSIS
EYEPOINT PHARMACEUTICALS

# Data from DAVIO 2 Suggests Strong Anatomic Control with OCT Change Below 10 microns at Week 32 Compared to the Aflibercept Control







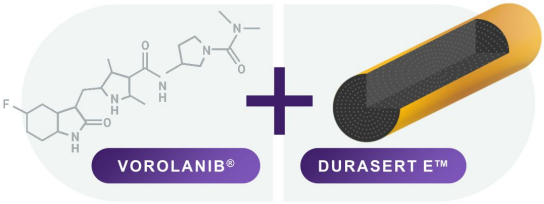
PRELIMINARY DATA – PENDING FINAL ANALYSIS

EyePoint PHARMACEUTICALS

# EYP-1901 Phase 2 DAVIO 2 Clinical Trial Met All Objectives

## MET PRIMARY ENDPOINT

- ✓ **Statistically non-inferior** change in BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2 mg and 3 mg dose
- ✓ **Continued favorable safety profile:**
  - No EYP-1901-related SAEs reported
  - Ocular AEs – majority are mild in severity and expected with mode of administration




## MET ALL SECONDARY ENDPOINTS

- ✓ **~80% reduction** in treatment burden at 6-months
- ✓ Nearly **two-thirds of eyes supplement-free** up to six-months
- ✓ **Strong anatomical control** in both EYP-1901 arms



PRELIMINARY DATA – PENDING FINAL ANALYSIS

# EYP-1901 Phase 2 DAVIO 2 Clinical Trial Met All Primary and Secondary Endpoints

| Endpoint | DAVIO 2 Topline | DAVIO 2 Lower Limit (as included in November deck) |
|---|---|---|
| **Mean change in BCVA vs. aflibercept control** | • - 0.3 letters (EYP-1901 2mg)<br>• - 0.4 letters (EYP-1901 3mg)<br>• Statistically non-inferior (CI 95%) | • < - 3.0 letters<br>• Potentially underpowered |
| **Safety** | • No reported EYP-1901-related ocular SAEs<br>• No reported EYP-1901- related systemic SAEs | Favorable safety profile |
| **Reduction in treatment burden** | • 89% (EYP-1901 2mg)*<br>• 85% (EYP-1901 3mg)* | 50% or better |
| **Supplement-free rate** | • 65% (EYP-1901 2mg)<br>• 64% (EYP-1901 3mg) | 50% or better |
| **Mean change in CST on OCT** | • + 15.1 microns (EYP-1901 2mg)<br>• + 10.6 microns (EYP-1901 3mg) | Within ~30 microns |




*vs. mean number of injections normalized 6 months prior to screening
PRELIMINARY DATA – PENDING FINAL ANALYSIS

EyePoint PHARMACEUTICALS

# EYP-1901 in wet AMD
# DAVIO 2 Phase 2 Clinical Trial Topline Data

December 4, 2023