

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) May 06, 2024

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

000-51122  
(Commission File Number)

26-2774444  
(IRS Employer  
Identification No.)

480 Pleasant Street  
Watertown, Massachusetts  
(Address of Principal Executive Offices)

02472  
(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 May 6, 2024, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing results for its Phase 2 PAVIA clinical trial for the potential treatment of moderately-severe to severe non-proliferative diabetic retinopathy (NPDR). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Additionally, on May 6, 2024, the Company posted an updated investor presentation on its website at [www.eyepointpharma.com](http://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	<a href="#">Press Release of EyePoint Pharmaceuticals, Inc. dated May 06, 2024</a>
99.2	<a href="#">Investor Presentation of EyePoint Pharmaceuticals, Inc. dated May 06, 2024</a>
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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**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: May 6, 2024

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

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**EyePoint Pharmaceuticals Announces Topline Data from the Phase 2 PAVIA Trial of DURAVYU™ in Non-Proliferative Diabetic Retinopathy**

– DURAVYU demonstrates stable or improved disease severity with reduced rates of NPDR progression at nine months –

– DURAVYU continues to demonstrate favorable safety and tolerability profile with no drug-related serious adverse events –

– Conference call to discuss the results to be held at 8:00 a.m. ET –

WATERTOWN, Mass., May 6, 2024 (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 topline results of its Phase 2 PAVIA clinical trial evaluating DURAVYU™ (vorolanib intravitreal insert), previously known as EYP-1901, in patients with non-proliferative diabetic retinopathy (NPDR). The data demonstrated that DURAVYU has a biologic effect in patients with NPDR with a favorable safety and tolerability profile, however the trial did not meet the pre-specified primary endpoint. The Company plans to provide an update on the path forward for DURAVYU as a potential treatment in NPDR following a review of the full 12-month data.

“The objective of the PAVIA trial was, for the first time, to evaluate DURAVYU as a potential treatment in a non-proliferative diabetic patient population,” said Jay Duker, M.D., Chief Executive Officer of EyePoint Pharmaceuticals. “Although the trial did not meet the pre-specified primary endpoint, we are encouraged that DURAVYU continues to be well tolerated and appears to reduce rates of NPDR progression at nine months. We plan to analyze the full twelve-month data once it is available to gain the clarity needed to assess the future of DURAVYU as a potential treatment for NPDR. I would like to thank the patients, the investigators and their site staff who participated in the PAVIA trial. We look forward to providing additional clinical and regulatory updates on the NPDR program in the coming months.”

Dr. Duker continued, “We remain laser focused on our preparation for the initiation of the LUGANO trial, the first pivotal, non-inferiority clinical trial for wet AMD, in the second half of this year. We remain confident that DURAVYU has the potential to change the treatment paradigm as a maintenance therapy for wet AMD patients based on the highly positive data seen in DAVIO 2, the largest intravitreal sustained release TKI study in wet AMD to date.”

**PAVIA topline interim results include:**

- 86% of patients in the 3mg arm and 80% of patients in the 2mg arm demonstrated stable or improved disease at nine months versus 70% in the control arm.
  - 0% of patients in the 3mg arm and 5% of patients in the 2mg arm worsened  $\geq 2$ -step at nine months vs. 10% in the control arm.
  - 5% of patients in the 3mg arm and 0% of patients in the 2mg arm achieved a  $\geq 2$ -step improvement in DRSS score at nine months versus 5% in the control arm.
  - Continued favorable safety and tolerability profile with no DURAVYU-related ocular or systemic serious adverse events reported.
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PAVIA is a 12-month, randomized, controlled Phase 2 clinical trial of DURAVYU in patients with moderately-severe to severe NPDR. The trial enrolled 77 patients randomly assigned to one of two doses of DURAVYU, or to the control group receiving a sham injection. DURAVYU is delivered with a routine intravitreal injection in the physician's office, similar to current FDA approved anti-VEGF treatments. The primary efficacy endpoint of the trial is improvement of at least two DRSS levels as of week 36 (approximately nine months) after the DURAVYU injection. Secondary endpoints include reduction in vision-threatening complications, occurrence of diabetic macular edema and/or proliferative disease, retinal ischemia/nonperfusion and safety. More information about the study is available at [clinicaltrials.gov](https://clinicaltrials.gov) (identifier: NCT05383209).

The Company remains on track to reach additional clinical milestones with DURAVYU with the initiation of the first Phase 3 pivotal trial in wet AMD, LUGANO, anticipated in the second half of 2024 and the second global Phase 3 pivotal trial in wet AMD, LUCIA, to follow, and with the readout of topline data from the Phase 2 VERONA trial in diabetic macular edema (DME) anticipated in the first quarter of 2025.

*DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.*

#### **Conference Call and Webcast Information**

EyePoint will host a conference call today, May 6, 2024 at 8:00 a.m. ET to discuss the results. To access the live conference call, please register at <https://register.vevent.com/register/B1460f77365f6c4d0cb4ea3f56f0ecd4>. A live audio webcast of the event can be accessed via the Investors section of the Company website at [www.eyepointpharma.com](http://www.eyepointpharma.com). A webcast replay will also be available on the corporate website at the conclusion of the call.

#### **About Non-proliferative Diabetic Retinopathy (NPDR)**

Diabetic retinopathy (DR) is a frequent complication of diabetes mellitus, and it is the leading cause of blindness in working age adults. DR affects approximately 40 percent of people with diabetes and is projected to impact 14.6 million Americans by 2050. Non-proliferative diabetic retinopathy (NPDR) is the early stage of the disease in which symptoms may be mild or nonexistent. In NPDR, the blood vessels in the retina are weakened, and tiny bulges in the blood vessels, called microaneurysms, may leak fluid into the retina. This leakage may lead to swelling of the macula and cause vision changes and blurriness. Those with moderately severe to severe NPDR are at high risk of progressing to proliferative diabetic retinopathy (PDR) and other vision-threatening complications including diabetic macular edema (DME) and neovascularization that can lead to blindness if left uncontrolled. The majority of patients with NPDR receive no course of treatment apart from observation by their eye doctor until their disease progresses to DME and/or PDR. This is largely because currently approved treatments are short-acting and therefore require frequent injections. A treatment with a convenient dosing regimen aligned to the cadence of a patient's visit to their eye doctor that proactively reduces the risk of progressing to a sight-threatening complication over the long term could help reduce the vision threatening effects of diabetic eye disease.

#### **About DURAVYU™ (vorolanib intravitreal insert)**

DURAVYU is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. DURAVYU 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 inhibitor, inhibiting all VEGF receptors. Further, in an in-vivo model of retinal detachment, vorolanib demonstrated neuroprotection, and it may have potential

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antifibrotic benefits as it also inhibits the PDGF receptor. DURAVYU is delivered by a routine intravitreal injection in the physician's office and is designed to fully elute vorolanib prior to complete bioerosion of the insert matrix to control release and allow for a redosing regimen. Once inserted, DURAVYU is immediately bioavailable, featuring an initial burst of drug, followed by near constant zero-order release kinetics for approximately nine months. Additionally, unlike currently approved biologics and other sustained release anti-VEGFs in development, DURAVYU is shipped and stored at ambient temperature.

DURAVYU is currently being evaluated in three ongoing Phase 2 clinical trials in wet age-related macular degeneration (wet AMD), non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME). In December 2023, the Company reported positive topline results from its Phase 2 DAVIO 2 clinical trial in wet AMD, which showed all primary and secondary endpoints were met. The data from the DAVIO 2 clinical trial supports the advancement of the wet AMD program into Phase 3 pivotal trials which are anticipated to initiate in the second half of 2024. Data from the Phase 2 PAVIA trial demonstrated stable or improved disease severity with reduced rates of NPDR progression at nine months and a continued favorable safety profile. The Phase 2 VERONA trial in DME is fully enrolled with topline data anticipated in the first quarter of 2025.

Vorolanib is licensed to EyePoint exclusively by Equinox Sciences, a Betta Pharmaceuticals affiliate, for the localized treatment of all ophthalmic diseases outside of China, Macao, Hong Kong and Taiwan.

### **About EyePoint Pharmaceuticals**

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical-stage biopharmaceutical 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, DURAVYU, is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert E™. Pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases. The proven Durasert® drug delivery technology has been safely administered to thousands of patient eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

### **Forward Looking Statements**

EYEPOINT PHARMACEUTICALS 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 statements about the sufficiency of our existing cash resources through topline data for Phase 3 clinical trials for DURAVYU™ in wet AMD; our expectations regarding the timing and clinical development of our product candidates, including DURAVYU and EYP-2301; the potential for DURAVYU 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

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**Exhibit 99.1**

(FDA) regulatory approval of DURAVYU 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.

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# DURAVYU™ in NPDR PAVIA Phase 2 Clinical Trial Topline Results

May 6, 2024



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DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.



# Legal Disclaimers

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 through topline data for Phase 3 clinical trials for DURAVYU™ in wet AMD; our expectations regarding the timing and clinical development of our product candidates, including DURAVYU and EYP-2301; the potential for DURAVYU 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.

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

## Pipeline represents potential multi billion-dollar opportunities using our bioerodible Durasert E™ IVT delivery technology

- **DURAVYU™ (vorolanib intravitreal insert)** – vorolanib, a selective and patented TKI in Durasert E™
  - Positive topline Phase 2 data in **wet AMD**
  - First Phase 3 trial in **wet AMD** planned to initiate in 2H 2024
  - Topline Phase 2 data in **NPDR**; 12-month data expected in 3Q 2024
  - Topline Phase 2 data in **DME** anticipated in Q1 2025
- **EYP-2301** – razuprotafib, a patented TIE-2 agonist for serious retinal diseases in Durasert E™

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

- Bioerodible Durasert E™ and non-erodible formulations
- Safely administered to thousands of patient eyes across four FDA approved products with non-erodible formulations

## Strong Balance Sheet

- **\$331M** of cash and investments on December 31, 2023
- Cash runway through Phase 3 wet AMD pivotal trials topline data in 2026

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IVT, intravitreal injection



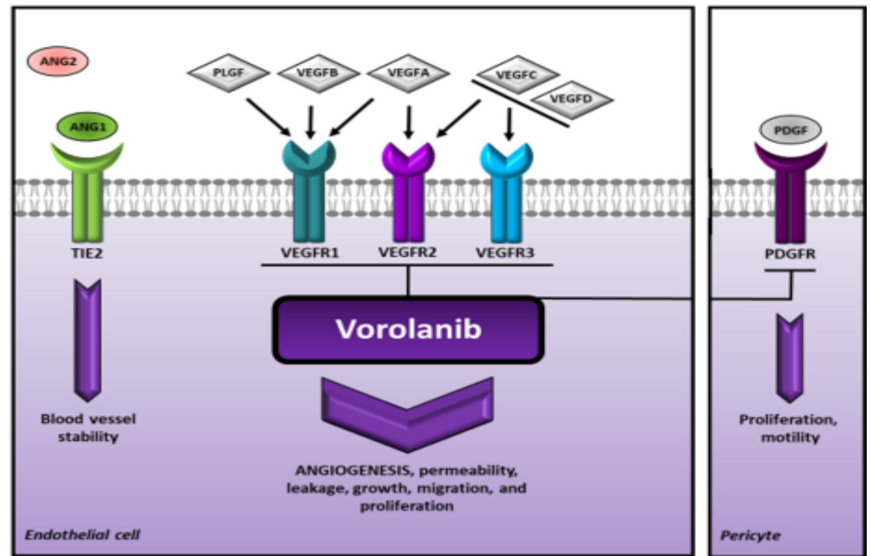
# Potential Multi Billion-Dollar Product Opportunities Leveraging Innovative Drug Delivery Technology, Bioerodible Durasert E™

Durasert E™ Programs	Indication	Discovery	Pre-Clin	Phase 1	Phase 2	Phase 3	Next Milestone
DURAVYU (EYP-1901) – vorolanib in Durasert E™ (tyrosine kinase inhibitor)	Wet AMD	single-dose, 6-month maintenance therapy					First pivotal Phase 3 2H 2024
	NPDR	single-dose, 9-month treatment					12-month data 3Q 2024
	DME	single-dose, 6-month treatment					Topline data in Q1 2025
EYP-2301 – razuprotafib in Durasert E™ (TIE-2 agonist)	serious retinal diseases	non-clinical					Pre-clin tox and PK data
Complement inhibition	GA	non-clinical					Potential product candidate in 2024

non-clinical      trial underway

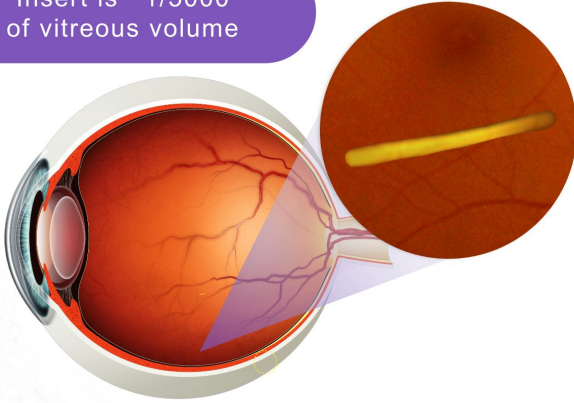
# Vorolanib Brings a Potential New MOA to the Treatment of VEGF-Mediated Retinal Diseases by Inhibiting all Isoforms of VEGF and PDGF

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



# DURAVYU: VEGF Receptor Binding Vorolanib In Bioerodible Durasert E™

Insert is ~1/5000  
of vitreous volume



- **Positive efficacy** data in wet AMD from Phase 1 DAVIO and Phase 2 DAVIO 2 clinical trials
- **Favorable safety profile with no ocular or systemic DURAVYU-related SAEs** reported in ongoing Phase 2 clinical trials
- **Immediately** bioavailable featuring an initial burst of drug followed by zero order kinetics release for ~9 months
- Vorolanib fully eluted prior to complete bioerosion of the matrix to **control release** and allow **redosing** regimen
- Delivered in the physician office via **routine intravitreal injection**
- Shipped and stored at **ambient temperature**



# Phase 2 PAVIA Clinical Trial Topline Results

**A RANDOMIZED, MULTICENTER  
TRIAL VERSUS SHAM CONTROL**



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# The PAVIA Clinical Trial in NPDR

A clinical trial evaluating two doses of DURAVYU against a sham control as a 9-month therapy

## **Design:**

Multi-center, randomized, double-masked, single injection of DURAVYU compared to sham control in patients with moderately-severe to severe NPDR without active CI-DME

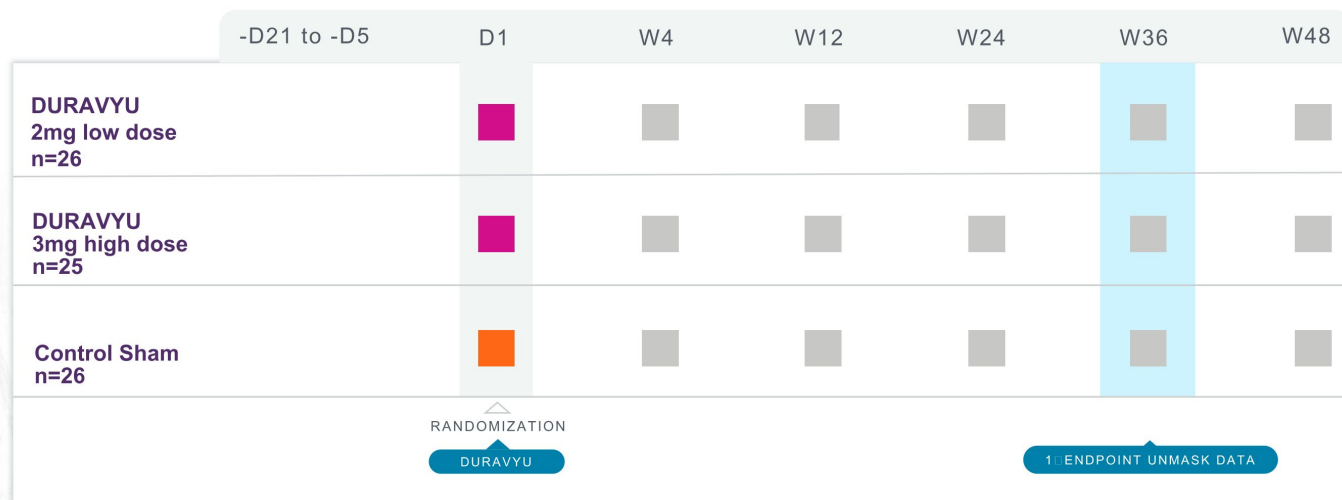
## **Primary outcome:**

Percentage of patients with a  $\geq 2$  step DRSS improvement score at week 36 (9 months) as evaluated by an independent reading center

## **Key secondary endpoints:**

- Reduction in vision-threatening complications
- CI-DME occurrence
- Safety

# Phase 2 PAVIA is a Randomized, Double-Masked, Single Injection of DURAVYU Compared to Sham Control

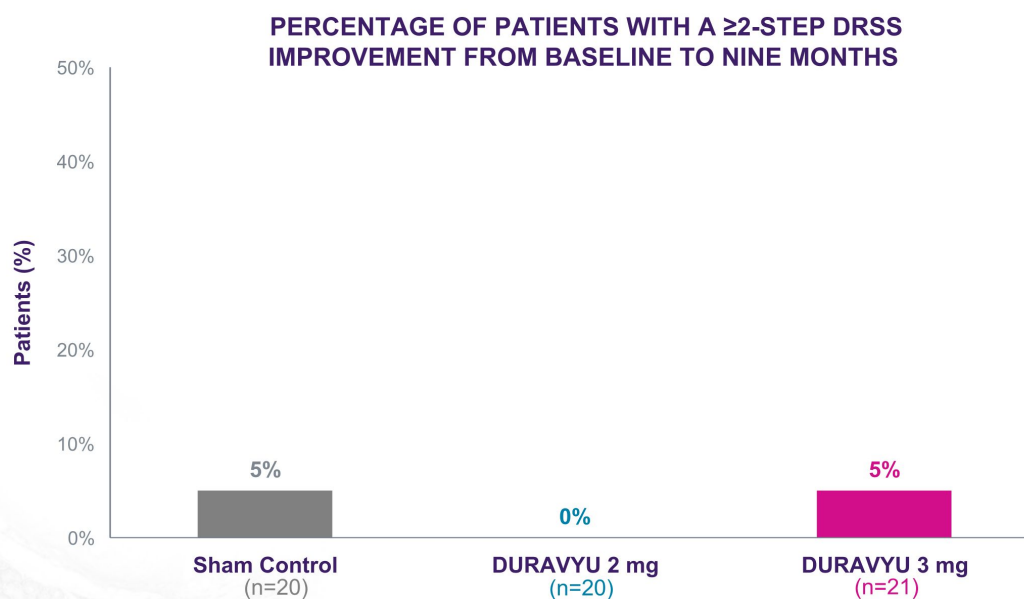




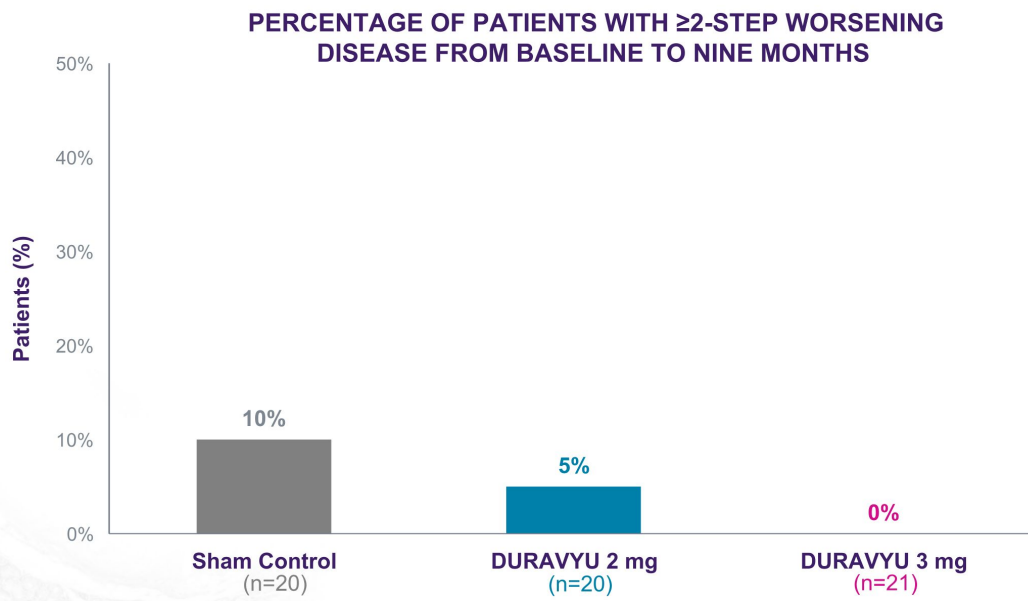
# PAVIA Baseline Characteristics Balanced Across Arms

	Control Sham (n=26)	DURAVYU 2mg (n=26)	DURAVYU 3mg (n=25)
Mean age, years (range)	56.9 (29-83)	56.8 (24-73)	60.2 (34-81)
Female, %	50.0	46.2	36.0
DRSS score, % Moderately-severe NPDR (score of 47) Severe NPDR (score of 53)	53.8 46.2	65.4 34.6	56.0 44.0
Mean BCVA, ETDRS letters (range)	81.3 (69-90)	83.2 (68-90)	81.8 (67-95)
Mean CST, $\mu\text{m}$ (range)	273.9 (199-329)	265.8 (193-319)	282.7 (201-325)
Median duration of diabetes (DM), years (range)	14.5 (0.3-29.1)	13.8 (0.3-46.3)	15.9 (0.3-42.3)

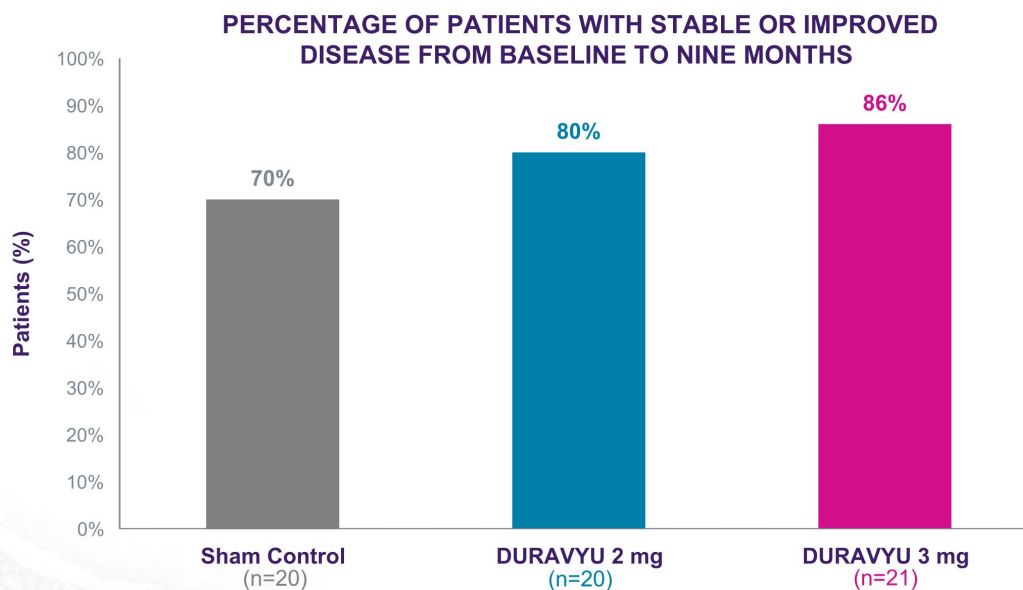
# Phase 2 PAVIA Trial Primary Endpoint: Percentage of Patients with a $\geq 2$ step DRSS Improvement



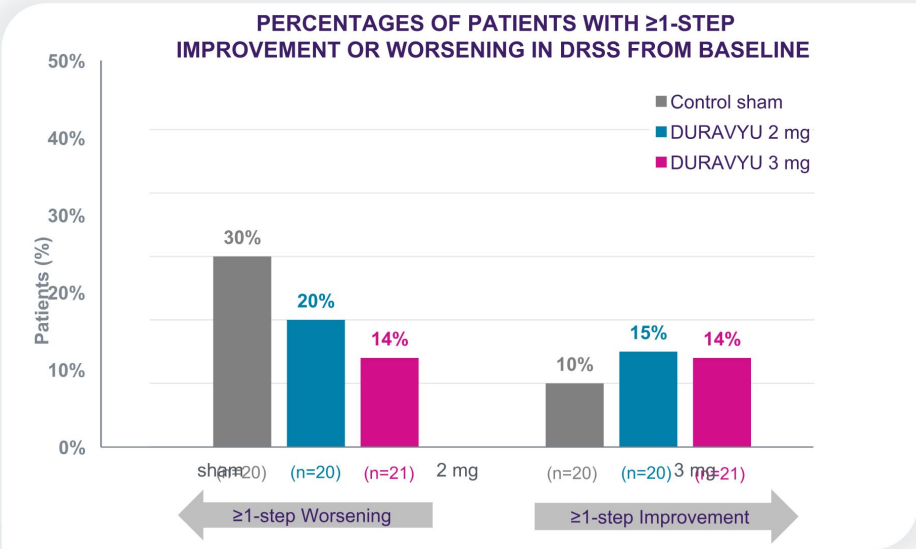
# Eyes Treated with DURAVYU had Reduced Rates of Disease Progression at Nine Months



# ~80% of Eyes Treated with DURAVYU Had Stable or Improved Severity of Disease at Nine Months



# DURAVYU Reduced Rates of NPDR Progression at Nine Months



# DURAVYU Demonstrated a Favorable Safety Profile in the Phase 2 PAVIA Trial

- No reported drug-related ocular SAEs
  - Two ocular SAEs reported in a study eye, deemed not drug-related by investigators:
    - Conversion of NPDR to PDR in the sham control arm
    - Hemorrhagic posterior vitreous detachment (PVD) eight-weeks after dosing in the DURAVYU 2mg arm
- No reported drug-related systemic SAEs
- No cases of:
  - Insert migration into the anterior chamber
  - Endophthalmitis
  - Retinal vasculitis (occlusive or non-occlusive)
- Low patient discontinuation rate up to week 36, none related to treatment with DURAVYU

# Phase 2 PAVIA Clinical Trial Demonstrated a Biologic Effect with a Favorable Safety and Tolerability Profile

## Efficacy

- DURAVYU demonstrated stable or improved disease severity with reduced rates of NPDR progression at nine months
  - 86% of patients in the 3mg arm and 80% of patients in the 2mg arm demonstrated stable or improved disease at nine months vs. 70% in the control arm
  - 0% of patients in the 3mg arm and 5% of patients in the 2mg arm worsened  $\geq 2$ -steps at nine months vs. 10% in the control arm
- Similar proportions of participants treated with DURAVYU and sham injection achieved  $\geq 2$ -step improvement in DRSS score at nine months

## Safety

- Continued favorable safety and tolerability profile with no drug-related ocular or systemic SAEs
- Overall, rates of ocular TEAEs were comparable between DURAVYU and control arm
- No cases of endophthalmitis or retinal vasculitis (occlusive or non-occlusive) were observed
- Two ocular SAEs reported in a study eye, deemed not drug-related by investigators
- Low patient discontinuation rate up to week 36, none related to treatment with DURAVYU

# DURAVYU™ in NPDR PAVIA Phase 2 Clinical Trial Topline Results

May 6, 2024



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PHARMACEUTICALS

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