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) June 26, 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)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D 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:

	Trading	
Title of each class	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 \Box

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 2.02 Results of Operations and Financial Condition.

On June 26, 2024, EyePoint Pharmaceuticals, Inc. (the "Company") posted the Company's 2024 R&D Day Presentation (the "Presentation") on its website at <u>www.eyepointpharma.com</u>, which Presentation included the Company's estimated cash and investments on hand as of June 30, 2024 and certain other corporate updates. The amounts included in the Presentation were calculated prior to the completion of a review by the Company's independent registered public accounting firm and are therefore subject to change upon completion of the Company's quarterly report for the period ended June 30, 2024. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of June 30, 2024.

Item 8.01 Other Events.

A copy of the Presentation is filed as Exhibit 99.1 hereto and is incorporated by reference herein.

On June 26, 2024, the Company issued a press release announcing certain clinical and regulatory developments for its lead pipeline program, DURAVYUTM (vorolanib intravitreal insert), formerly known as EYP-1901, its Durasert E^{TM} sustained drug delivery technology and early-stage programs to be presented during the Company's R&D Day. A copy of the press release 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	R&D Presentation of EyePoint Pharmaceuticals, Inc. dated June 26, 2024
99.2	Press Release of EyePoint Pharmaceuticals, Inc. dated June 26, 2024
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: June 26, 2024

By: /s/ George O. Elston

George O. Elston Executive Vice President and Chief Financial Officer EYEPOINT PHARMACEUTICALS R&DDAY 2024 •

UNIVERSITY CLUB | NEW YORK CITY | JUNE 26, 2024



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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 forwardlooking 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 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.

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INTRODUCTIONS AND AGENDA

JAY DUKER, MD I PRESIDENT AND CHIEF EXECUTIVE OFFICER



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R&D Day Speakers: Management



R&D Day Speakers: KOL Guest Speakers



R&D Day: Agenda (1/2)

	PRESENTATION SPEAKER
Introductions	Jay Duker, M.D.
Company Overview	Jay Duker, M.D.
DURAVYU™ (vorolanib intravitreal insert) Overview	Jay Duker, M.D.
DURAVYU™: Phase 2 DAVIO 2 Clinical Results and Sub Group Analyses	Yasha S. Modi, M.D.
DURAVYU™: Phase 2 DAVIO 2 12-Month Topline Result	s Carl D. Regillo, M.D.

R&D Day: Agenda (2/2)

	PRESENTATION SPEAKER
DURAVYU™: Pivotal Phase 3 Plans for Wet AMD	Jay Duker, M.D. Ramiro Ribeiro, M.D., Ph.D.
Early Pipeline	Jay Duker, M.D.
Key Opinion Leader Insights and Discussion	Jay Duker, M.D. Carl D. Regillo, M.D. Yasha S. Modi, M.D.
Q&A	All
Closing Remarks	Jay Duker, M.D. Ramiro Ribeiro, M.D., Ph.D.

R&D Day: Agenda

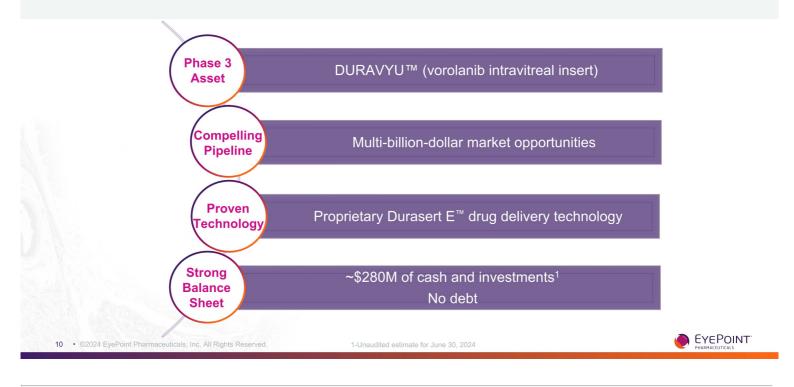
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COMMITTED TO DEVELOPING THERAPEUTICS TO IMPROVE THE LIVES OF PATIENTS WITH SERIOUS RETINAL DISEASES

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Phase 3 Clinical Stage Company Leveraging Proven Delivery Technology



Pipeline Represents Potential Multi Billion-Dollar Product Opportunities

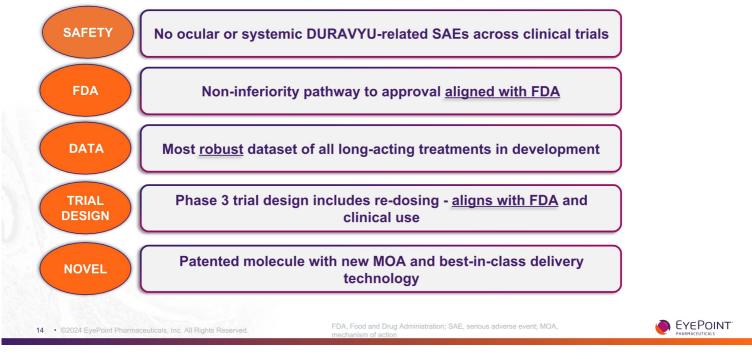
Durasert E [™] Programs	Indication	Discovery	Pre-Clin	Phase 1	Phase 2	Phase 3	Next Milestone
	Wet AMD	STATIS	STICALLY NO		o soc	•	First Phase 3 Trial 2H 2024
DURAVYU (EYP-1901) – vorolanib in Durasert E™ (tyrosine kinase inhibitor)	NPDR		BIOLOGIC EFF INUED FAVOF	ECT AND	Y		12-month data Q3 2024
	DME			LED			Topline data in Q1 2025
EYP-2301 – razuprotafib in Durasert E™ (TIE-2 agonist)	serious retinal diseases						Pre-clin tox and PK data
Complement inhibition	GA						Potential product candidate in 2024
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R&D Day: Agenda

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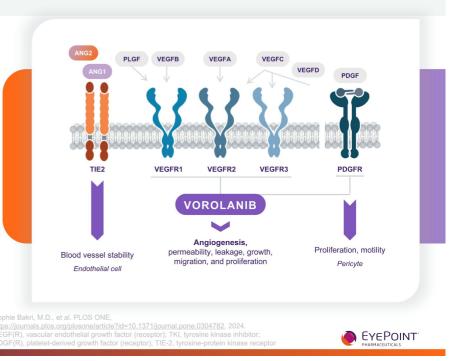
DURAVYU entering Phase 3 with robust dataset and FDA alignment on approval pathway



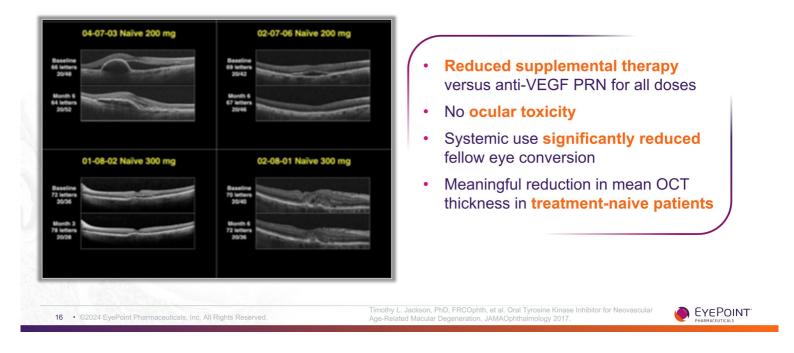
Vorolanib is a Potent and Highly Selective Pan-VEGF Receptor Inhibitor

- Best-in-class TKI
- Composition of matter
 patent into 2037
- Demonstrated
 neuroprotection
- Potential antifibrotic
- Does not inhibit TIE-2¹

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Vorolanib Demonstrated Compelling Clinical Activity in wet AMD Delivered Orally



DURAVYU: Vorolanib in Bioerodible DurasertE[™]



DURAVYU Demonstrated Clinically Meaningful Safety and Efficacy Outcomes Across Multiple Indications

Trial	n size	Indication	Safety	Key Efficacy Outcomes
OAVIO	17	wet AMD		 Stable BCVA and OCT 74% reduction in treatment burden
DAVIO 2	161	wet AMD	Favorable safety profile No DURAVYU	 Statistically non-inferior BCVA >80% reduction in treatment burden Stable OCT
PAVIA	77	NPDR	related ocular or systemic SAEs	 Stable to improved disease severity up to 9- months; trial continuing 12 months
/ERONA	27	DME		• Trial underway
VERONA	21	DIME	Interim, masked safety	

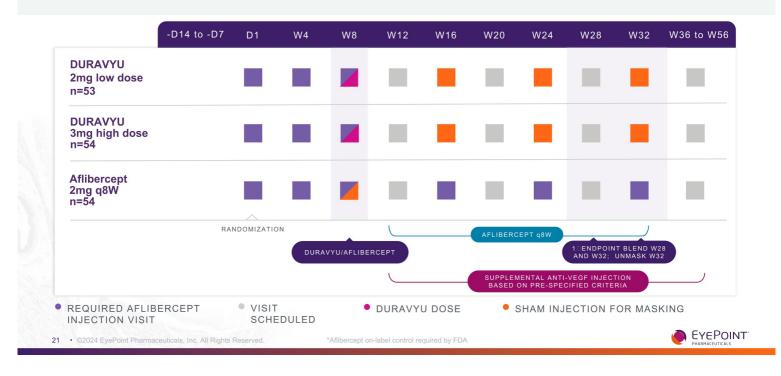
DURAVYU HAS BEEN TESTED IN 191 PATIENTS TO DATE ACROSS DIFFERENT INDICATIONS

R&D Day: Agenda

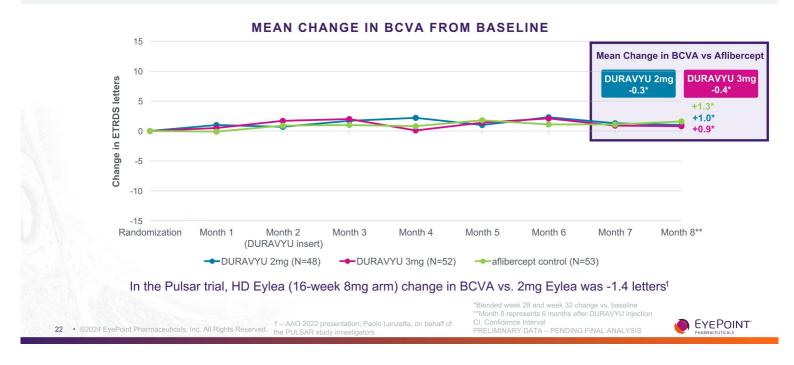
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1 Many patients with wet AMD are chronically Q undertreated >80% of Retina Specialists say undertreatment is due to patient noncompliance, scheduling limitations or There is a provider preference for less frequent dosing¹ Significant Current "treat and extend" protocol still places significant burden on physicians and patients **Need for More** Chronic disease treated with short acting anti-VEGF • biologics Durable A delay in care/missed visit can result in vision Therapies in loss A delay in treatment of only 5.34 weeks resulted in . Wet AMD vision loss² 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 States³ 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 20 ©2024 EyePoint Pharmaceuticals, Inc. All Rights Reserved.

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



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



Clinically Meaningful Reduction in Treatment Burden Retrospectively Supports DURAVYU as a Maintenance Treatment For Wet AMD

	DURAVYU 2mg	DURAVYU 3mg
Mean number of injections week 8 through week 32	0.55	0.73
Mean number of injections 6 months prior to screening*	4.98	5.02
Reduction in treatment burden vs. 6 months prior (%)	89%	85%

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*Normalized PRELIMINARY DATA – PENDING FINAL ANALYSIS

EYEPOINT

DURAVYU Demonstrated a Meaningful Reduction in Treatment Burden Prospectively vs. the Aflibercept Control Arm

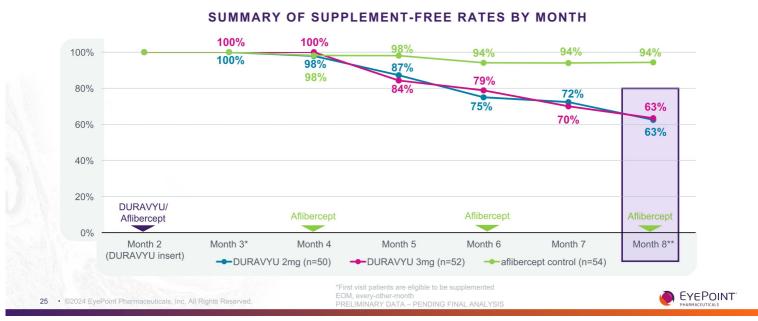
	DURAVYU 2mg	DURAVYU 3mg	Aflibercep 2mg q8W
Mean number of injections week 8 through week 32	0.55	0.73	3.28
Reduction in treatment burden vs. aflibercept control (%)	83%	78%	NA

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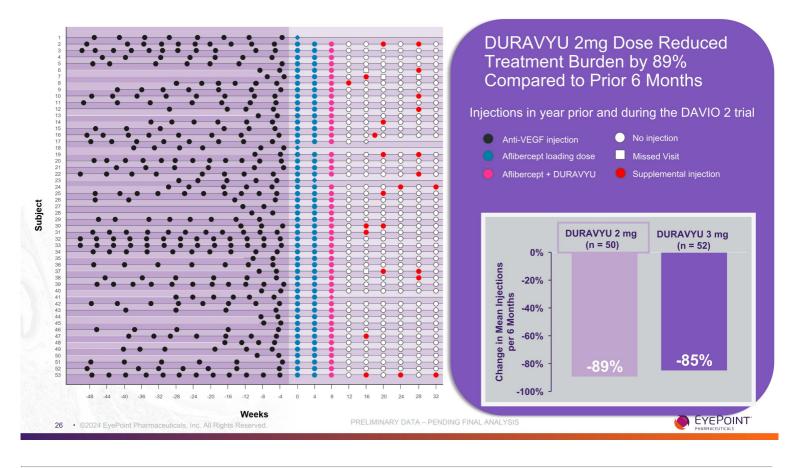
PRELIMINARY DATA - PENDING FINAL ANALYSIS

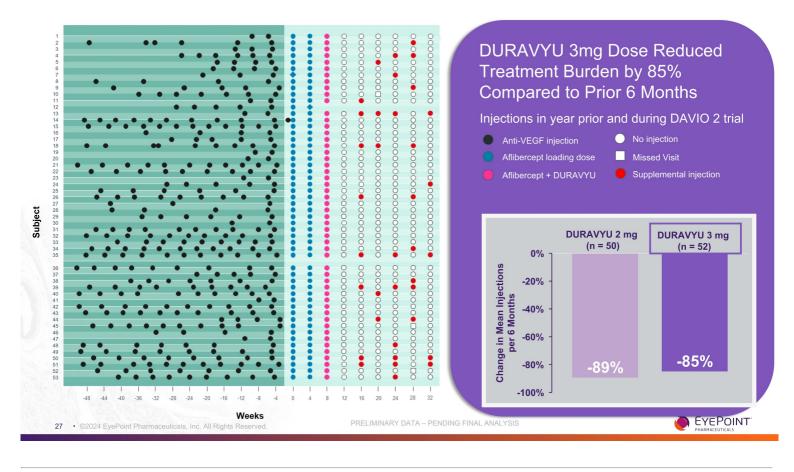
EYEPOINT

Nearly Two-Thirds of Eyes Treated with DURAVYU were Supplement-Free up to Six Months

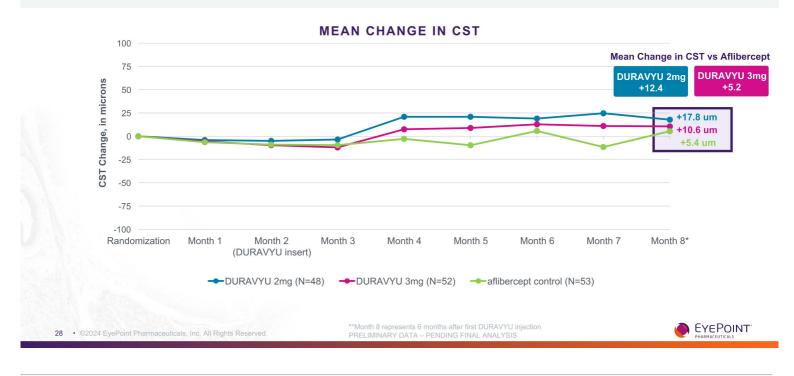


DESPITE EOM AFLIBERCEPT INJECTIONS, 6% OF THE CONTROL GROUP REQUIRED ADDITIONAL SUPPLEMENTATION

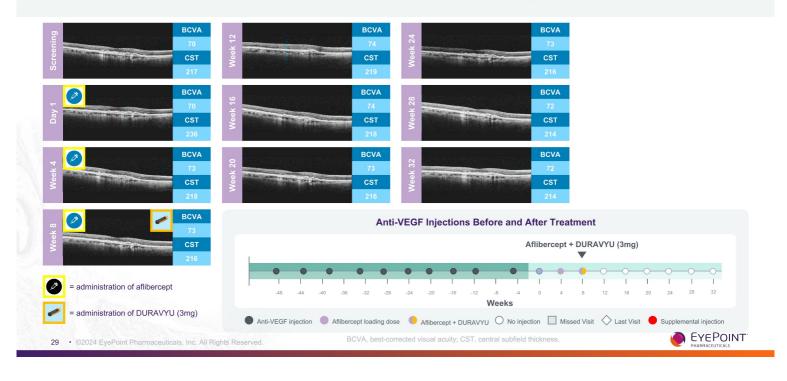




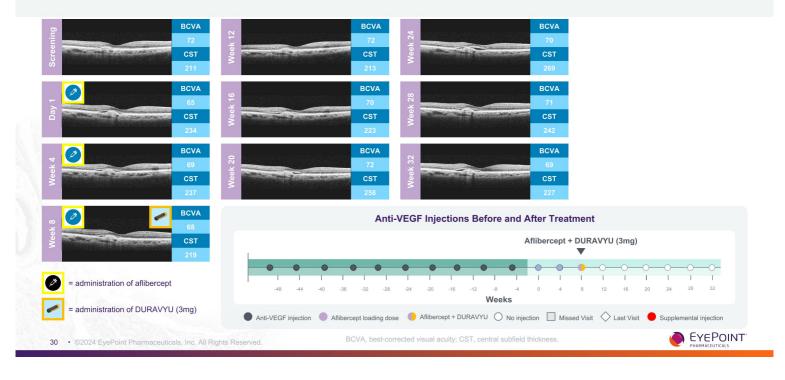
Data from DAVIO 2 Suggests Strong Anatomic Control at 6-Months Compared to the Aflibercept Control



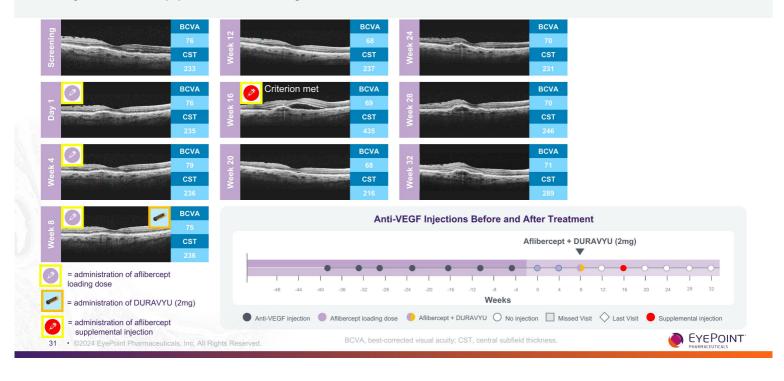
DAVIO 2 Case Study: Patient with Frequent Anti-VEGF Injections Was Maintained for at Least Six Months After Receiving DURAVYU



DAVIO 2 Case Study: Patient Treated with DURAVYU had Fluctuations in Fluid without Impact on Vision



DAVIO 2 Case Study: Patient Treated with DURAVYU Remained Dry with Only One Supplemental Injection



DURAVYU Phase 2 DAVIO 2 Clinical Trial in Wet AMD Met All Primary and Secondary Endpoints

ndpoint	2mg	3mg
Primary: Non-inferior change in BCVA vs. aflibercept	- 0.3 letters	- 0.4 letters
Secondary: Favorable safety profile ¹	No DURAVYL	J-related SAEs
Secondary: Reduction in treatment burden vs. 6 mos prior	89%	85%
Secondary: Reduction in treatment burden vs. aflibercept	83%	78%
Secondary: Supplement-free up to 6 months	63% 88% of eyes had 0 or only 1 supplemental injections	63% 83% of eyes had 0 or only 1 supplemental injections
Secondary: Anatomical control vs. aflibercept	+12.4um	+5.2um

PHASE 2 DAVIO 2 TRIAL IN WET AMD

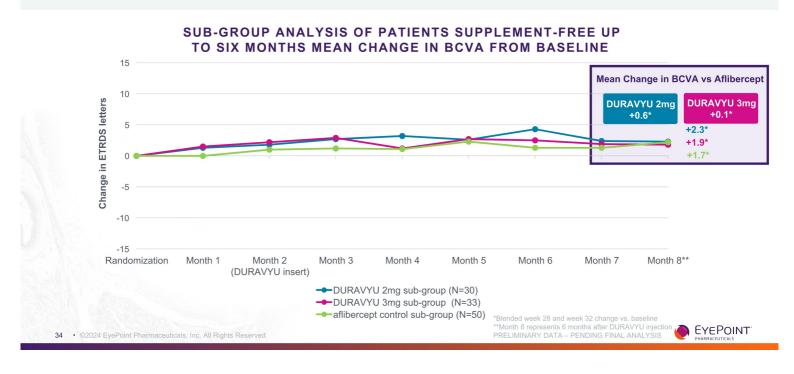
SUB-GROUP ANALYSIS



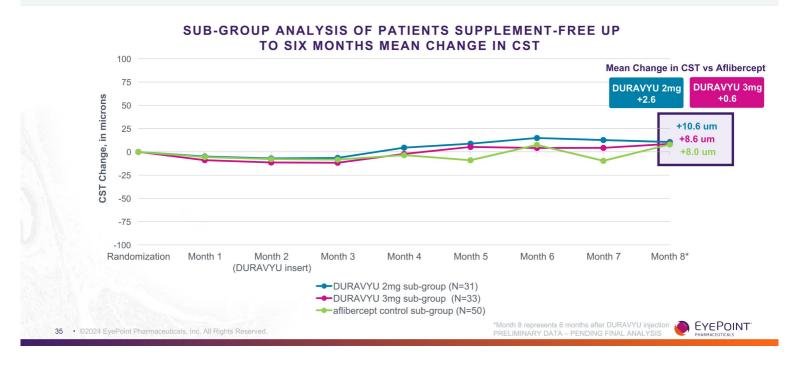
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Sub-Group Analysis of Supplement-Free Patients Demonstrated Eyes Treated with DURAVYU had Numerically Better Visual Acuity vs. Control

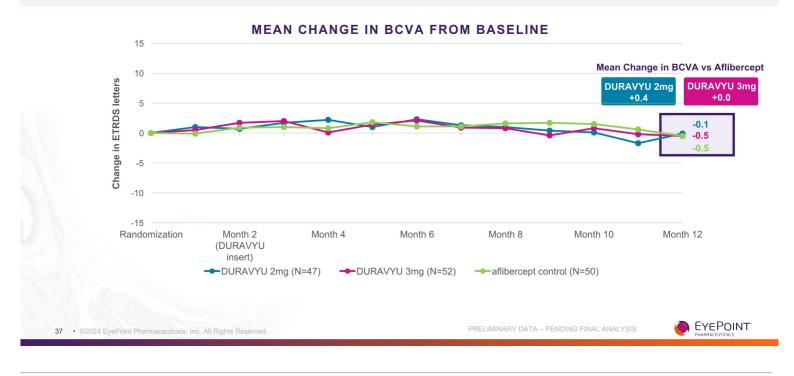


Sub-Group Analysis of Supplement-Free Patients Demonstrated Strong Anatomic Control Up to 6-Months Compared to the Aflibercept Control

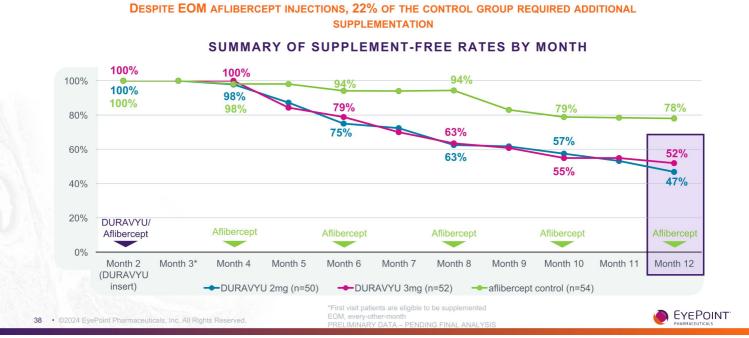


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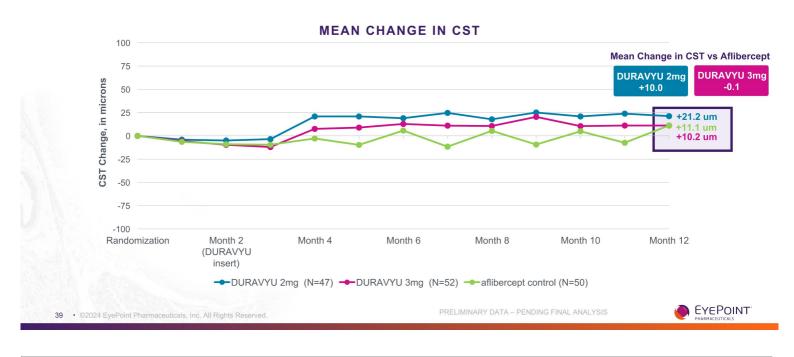
Nearly Identical BCVA Compared to Aflibercept Through 12-Months After a Single Injection; Statistically Significant (95% CI)



Clinically Meaningful Supplement-Free Rates in DURAVYU Treated Eyes After Single Injection



Data from DAVIO 2 Demonstrates Strong Anatomic Control in Eyes Treated with DURAVYU without Saw-Toothing Seen in Aflibercept Arm



DURAVYU Demonstrated a Favorable Safety Profile in the Phase 2 DAVIO 2 Clinical Trial

- No DURAVYU-related ocular or systemic SAEs
- No insert migration into the anterior chamber
- No retinal occlusive vasculitis
- · Low patient discontinuation rate
 - No discontinuations were related to DURAVYU treatment

Data as of June 14, 2024

🦲 ΕΥΕΡΟΙΝΤ

Topline 12-Month DAVIO 2 Data Underscores Highly Positive Results

Efficacy:

- After a single injection, eyes treated with DURAVYU maintained stable visual acuity with strong anatomical control
- Approximately half of DURAVYUtreated eyes were supplement-free up to 12 months

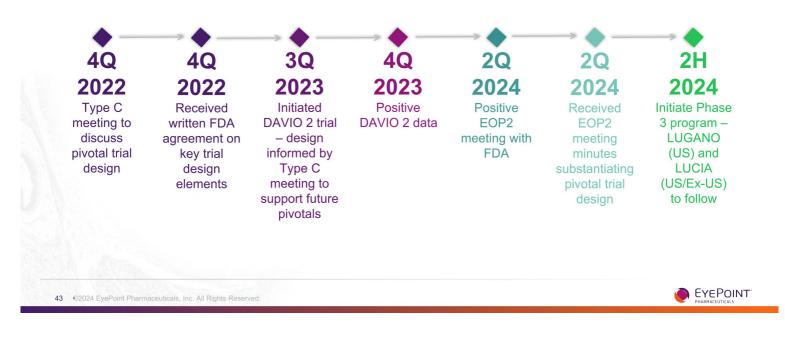
Safety:

• No ocular or systemic DURAVYUrelated SAEs



DURAVYU™: Pivotal Phase 3 Plans for Wet AMD	Jay Duker, M.D. Ramiro Ribeiro, M.D., Ph.D.
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Clear Regulatory Pathway for Phase 3 Pivotal Trials in wet AMD Informed by Multiple FDA Interactions



Phase 3 Trials are Designed to Enable Global Regulatory Approval of DURAVYU

LUGANO/LUCIA: GLOBAL, RANDOMIZED, DOUBLE-MASKED, AFLIBERCEPT CONTROLLED

• Two arms: 2.7mg DURAVYU vs. aflibercept control		OBJECTIVE Demonstrate DURAVYU, when administered every six months , achieves similar visual outcomes to	 DESIGN Two pivotal, non-inferiority trials ~400 patients per trial 	
ENDPOINTS		on-label aflibercept while reducing treatment burden	aflibercept control	
Primary Endpoint: difference in mean change in BCVA from Day 1 to Week 52 and 56 (blended) versus aflibercept control			hange in BCVA from Day 1 to Week 52 and 56	
Secondary endpoints: safety, reduction in treatment burden, percent of eyes supplement-free, anatomical stability				
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Phase 3 Program is Designed to Drive Global Regulatory and Commercial Success

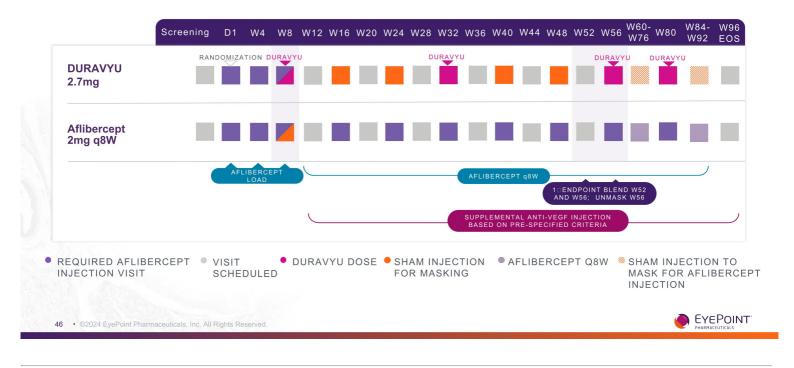
KEY TRIAL DESIGN ELEMENTS -

- Only sustained release wet AMD program to evaluate reinjection for label
- Trials will enroll patients with active wet AMD (previously treated and treatment naïve)
- · All patients will receive three loading doses of aflibercept
- Sham injections will be used for masking
- Primary efficacy endpoint at 12 months (basis for NDA submission)
 - Safety will be monitored for 24 months

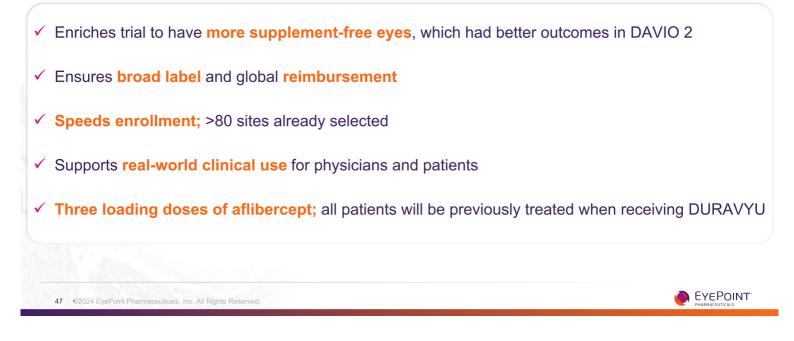
On track to be first sustained release wet AMD program with two pivotal trials to enable NDA submission to the FDA

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DURAVYU in Wet AMD Phase 3 Pivotal Trial Design



A Broad Patient Population in the Phase 3 Pivotal Trials has the Potential to Enhance Trial Outcomes and Increase Commercial Opportunity



A Broad Patient Population in the Phase 3 Pivotal Trials has the Potential to Enhance Trial Outcomes and Increase Commercial Opportunity

Highly positive, statistically non-inferior DAVIO 2 results despite tough to treat population

- Average of 10 injections per year prior to enrollment
- Aflibercept arm (q8w) had nearly 25% supplementation rate despite receiving on-label injections
- Supplement-free eyes did the best visually and, in those eyes, DURAVYU performed numerically better than aflibercept visually

In DAVIO 2, eyes that were pseudo naïve¹ had fewer supplements than the overall cohort

We believe the inclusion of treatment naive patients not only expands the potential patient population but also increases the probability of success

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1. Patients diagnosed ≤1 year with ≤2 prior $\alpha VEGF$ injections

Commercial Manufacturing Facility





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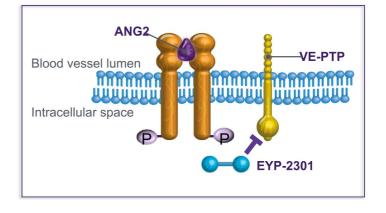
EYP-2301: Razuprotafib in Durasert E[™] is a Patented TIE-2 Agonist as a Potential New MOA for Treating Serious Retinal Diseases

EYP-2301 targets vascular endothelial protein tyrosine phosphatase (VE-PTP) to promote TIE-2 activation and maintain vascular stability in the retina

- Tie-2 activation combined with VEGF inhibition has the potential to enhance efficacy and extend durability¹ of treatment
- Razuprotafib (f/k/a AKB-9778) delivered subcutaneously demonstrated preclinical and clinical proof of concept in posterior segment disease ^{2,3}

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1. Heier et al. Retina, 2021;41:1-19. and Joussen et al. Eye 2021; 35:1305-1316.; 2. Hammer Al – Diabetes.2011 Jan 1; 3. Shen et al. JCI, 2014; 124:4564; 4. Campochiaro et al. Ophthalmology, 2016; 123:1722-1730



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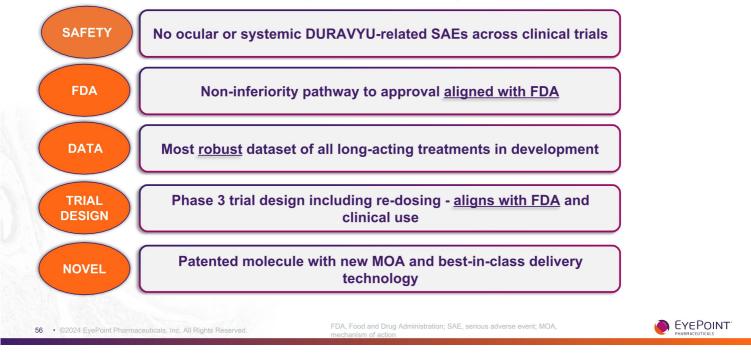
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All
Jay Duker, M.D. Ramiro Ribeiro, M.D., Ph.D.

Data from Clinical and Preclinical Studies will be Presented at Multiple Upcoming Meetings

Medical Conference	Data	Timing
ASRS	New DAVIO 2 sub-group analyses	July 2024
American Retina Forum	Encore presentation of XX data	August 2024
Retina Society	Topline DAVIO 2 12-month data	September 2024
EURetina	DAVIO 2 sub-group analyses Topline DAVIO 2 12-month data	September 2024
AAO	DAVIO 2 12-month sub-group analyses	October 2024
FloRetina	TBD	December 2024
Publications		Link
in Patients With Wet Age-Relate	1 Bioerodible, Sustained-Delivery Vorolanib Insert ed Macular Degeneration et al. <i>Ophthalmology Science.</i> 2024 Apr 8:4(5)	https://www.ophthalmologyscience.or g/article/S2666-9145(24)00063- 0/fulltext
growth factor receptor inhibitors	b: A comparative study of vascular endothelial s and their anti-angiogenic effects ks M, et al. <i>PLOS One</i> . 2024 June 4	https://journals.plos.org/plosone/articl e?id=10.1371/journal.pone.0304782
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DURAVYU entering Phase 3 with robust dataset and FDA alignment on approval pathway



EYEPOINT PHARMACEUTICALS R&D DAY 2024 •

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EyePoint Pharmaceuticals to Highlight DURAVYUTM (vorolanib intravitreal insert) Clinical and Regulatory Progress and Pipeline Innovation at R&D Day 2024

- Phase 3 trial design for the LUGANO and LUCIA pivotal non-inferiority trials of DURAVYU in wet AMD based on positive EOP2 meeting with FDA; on track for trial initiation in 2H 2024 -

- Positive twelve-month safety and efficacy data from Phase 2 DAVIO 2 clinical trial evaluating DURAVYU for the treatment of wet AMD reinforcespotential as a sustained six-month maintenance therapy –

- Phase 2 trial of DURAVYU in diabetic macular edema (DME) fully enrolled -

- EyePoint to webcast its R&D Day event today at 8:00 a.m. ET -

WATERTOWN, Mass., June 26, 2024 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to help improve the lives of patients with serious retinal diseases, today announced the Company will highlight clinical and regulatory developments for its lead pipeline program, DURAVYUTM(vorolanib intravitreal insert), formerly known as EYP-1901, its Durasert E^{TM} sustained drug delivery technology, and early-stage programs during EyePoint's R&D Day today, Wednesday, June 26, 2024, from 8:00 a.m. to 9:30 a.m. ET.

"EyePoint continues to pioneer the development of sustained-release drug delivery treatments for serious retinal diseases with DURAVYU[™], a potentially paradigm-shifting, best-in-class treatment for patients suffering from VEGF-mediated retinal diseases," said Jay Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. "We have a track record of strong execution, establishing the most robust dataset among sustained delivery TKI programs in wet age-related macular degeneration. We are excited to share the positive twelve-month DAVIO 2 clinical trial data for DURAVYU, as well as our Phase 3 clinical trial plans for wet age-related macular degeneration (wet AMD), with first patient dosing anticipated in the second half of this year. Importantly, our planned Phase 3 design includes redosing, consistent with expected commercial use. We believe DURAVYU and our earlier-stage programs, including EYP-2301, are potentially multi-billion-dollar product opportunities, and we remain laser focused on advancing our mission of improving patient vision with innovative treatment options."

R&D Day will feature commentary from EyePoint's management team as well as key opinion leader (KOL) guest speakers, Carl D. Regillo, M.D., FACS, Professor of Ophthalmology at Thomas Jefferson University, Chief of Retina Service at Wills Eye Hospital, Founder of Wills Eye Clinical Retina Research Unit in Philadelphia, and Partner at Mid Atlantic Retina and Yasha S. Modi, M.D., Associate Professor of Vitreoretinal Surgery, Retinal Disease and Uveitis at New York University and Director of Teleretina.

R&D Day Highlights:

Phase 3 plans for DURAVYUTM in wet AMD, including key design elements of the Phase 3 LUGANO and LUCIA pivotal trials

- o Alignment on pathway to approval with U.S. Food and Drug Administration (FDA) based on positive End of Phase 2 meeting for two noninferiority trials, 6-month redosing of DURAVYU and sham for masking with a one-year endpoint.
- o Each trial is expected to enroll approximately 400 patients with active wet AMD, including previously treated and treatment naïve patients, randomly assigned to either a



- 2.7mg dose of DURAVYU or an on-label aflibercept control. All patients to receive three monthly loading doses of aflibercept prior to DURAVYU with randomization occurring on Day 1.
- o The LUGANO (US) trial remains on track to initiate in 2H 2024 with LUCIA (US/ex-US) to follow.

Positive twelve-month safety and efficacy data from the Phase 2 DAVIO 2 clinical trial evaluating DURAVYUTM for the treatment of wet AMD

- o Favorable safety profile No DURAVYU related ocular or systemic SAEs
- o **Best corrected visual acuity (BCVA)** Statistically significant visual acuity outcomes with both DURAVYU arms change in visual acuity nearly identical to aflibercept control arm through 12 months after a single injection of DURAVYU
- o Central Subfield Thickness (CST) Strong anatomical control through 12 months after a single injection of DURAVYU
- Supplement Free After a single injection of DURAVYU, approximately half of the treated study eyes were anti-VEGF supplement free, while 22% of the eyes in the aflibercept control arm were administered a supplement despite these control eyes receiving mandated bimonthly injections through 12 months
- The VERONA trial, a Phase 2 trial of DURAVYUTM in diabetic macular edema (DME) patients has completed enrollment with 27 patients assigned to one of two intravitreal doses of DURAVYU or an aflibercept control. To date, DURAVYU is well-tolerated with no reported drug-related ocular or systemic serious adverse events in this trial.

"We are very encouraged with the excellent safety and efficacy results from our Phase 2 DAVIO 2 trial. We believe there remains a significant opportunity for a safe and effective sustained delivery maintenance treatment in wet AMD, and we believe the DAVIO 2 trial data reinforces the potential for DURAVYU to maintain a majority of patients with active disease with no supplemental anti-VEGF therapy for six months or longer," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint Pharmaceuticals. "We look forward to enrolling patients in the Phase 3 LUGANO clinical trial for DURAVYU in wet AMD later this year, and we believe that with these DAVIO 2 results and our real-world-based pivotal trial design in-hand, we are in an excellent position to advance this innovative therapy and improve the lives of patients suffering from serious retinal diseases."

R&D Day Webcast Information

To access the live conference call, please register at <u>https://register.vevent.com/register/B110e9bca3aca34595a46c9a0e08ef92da</u>. A live webcast and subsequent archived replay of the presentation may be accessed via the Investors section of the Company website at <u>www.eyepointpharma.com</u>. The replay will be available for 90 days after the event.

About the Phase 2 DAVIO 2 and Phase 3 LUGANO and LUCIA Clinical Trials

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of DURAVYUTM 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 DURAVYU (approximately 2 mg or 3 mg) or an aflibercept control. DURAVYU 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 DURAVYU injection. Secondary endpoints include safety, change in CST as measured by optical coherence tomography (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 anticipates that the first patient in the Phase 3 LUGANO clinical trial of DURAVYU for wet AMD will be dosed in 2H 2024 and the LUCIA trial to follow. The pivotal trials are expected to enroll approximately 400 patients with active wet AMD each, including both previously treated and treatment naïve patients, randomly assigned to 2.7mg of DURAVYU versus an on-label aflibercept control. DURAVYU 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 LUGANO and LUCIA trials is non-inferiority to the aflibercept control, as measured by change in BCVA twelve-months after two DURAVYU injections that will be administered six-months apart. Secondary efficacy endpoints include change in CST as measured by OCT, time to first supplemental anti-VEGF, reduction in treatment burden and safety.

About DURAVYUTM

DURAVYUTM, previously known as EYP-1901, 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 may have antifibrotic benefits. DURAVYU is shipped and stored at ambient temperature and is administered with a standard intravitreal injection in the physician's office. DURAVYU is also immediately bioavailable with zero-order release kinetics release for approximately nine months.

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 ETMtechnology for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYUTM (previously known as EYP-1901), is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert ETM. Pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, formulated in Durasert ETM 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.

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.

 $DURAVYU^{M}$ 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.



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 EYP-1901 (DURAVYUTM) 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 (FDA) regulatory approval of DURAVYU and EYP-2301; the success of current and future license agreements; our dependence on contract research organizations, 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 forwardlooking 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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