### 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 provision                                                                          | 18:      |
| □ 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:                                                                                                                                                                                        |          |
| 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 the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).            | 12b-2 of |
| 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 fraccounting standards provided pursuant to Section 13(a) of the Exchange Act. | nancial  |

#### 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 <a href="https://www.eyepointpharma.com">www.eyepointpharma.com</a>, 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, DURAVYU<sup>TM</sup> (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



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. **EYEPOINT** 

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### R&D Day Speakers: Management



Jay Duker, MD President and CEO

>30 years managing retinal diseases and is a 12-time clinical trial investigator/co investigator; he has started three companies and has published >345 ophthalmic journal articles. Previous Director of the New England Eye Center (NEEC) and Professor and Chair of the Department of Ophthalmology at Tufts Medical Center and the Tufts University School of Medicine in Boston.



George O. Elston EVP and CFO

>25 years of diverse financial and executive leadership in the biopharmaceutical sector with strong record of execution across strategic, operational, financial goals to drive shareholder value. He has established strong relationships across wall street and pharma/biotech resulting in transformative company-building and M&A transactions.



Ramiro Ribeiro, MD, PhD CMO

Extensive experience encompassing clinical practice as a retina specialist, academia and the pharmaceutical industry with a strong track record of successfully bringing novel therapies to patients globally. Previous Head of Clinical Development at Apellis where he successfully led the end-to-end clinical process for FDA approval of SYFOVRE.



## R&D Day Speakers: KOL Guest Speakers



### Carl D. Regillo, MD, 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, Mid Atlantic



Yasha S. Modi, MD

Associate Professor of Vitreoretinal Surgery, Retinal Disease and Uveitis at New York University; Director of Teleretina

EYEPOINT

Note: Dr. Modi and Dr. Regillo are paid consultants to EyePoint and are being compensated for their

## 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-<br>Group Analyses | Yasha S. Modi, M.D.   |
| DURAVYU™: Phase 2 DAVIO 2 12-Month Topline Results                    | Carl D. Regillo, M.D. |

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.



## R&D Day: Agenda (2/2)

#### PRESENTATION SPEAKER

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



## R&D Day: Agenda

#### PRESENTATION SPEAKER

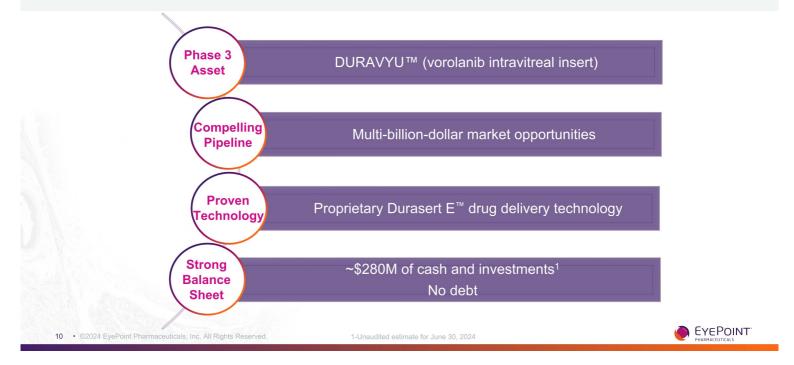
| Introductions                                                     | Jay Duker, M.D.       |
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# COMMITTED TO DEVELOPING THERAPEUTICS TO IMPROVE THE LIVES OF PATIENTS WITH SERIOUS RETINAL DISEASES



## 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  | N-INFERIOR T                                       | o soc   | •                       | First Phase 3 Trial<br>2H 2024      |
| DURAVYU (EYP-1901) –<br>vorolanib in Durasert E™<br>(tyrosine kinase inhibitor) | NPDR                        |                | BIOLOGIC EFF | FECT AND<br>RABLE SAFET                            | Υ       |                         | 12-month data Q3<br>2024            |
|                                                                                 | DME                         | FULLY ENROLLED |              |                                                    |         | Topline data in Q1 2025 |                                     |
| EYP-2301 – razuprotafib in<br>Durasert E™<br>(TIE-2 agonist)                    | serious retinal<br>diseases |                |              |                                                    |         |                         | Pre-clin tox and PK data            |
| Complement inhibition                                                           | GA                          |                |              |                                                    |         |                         | Potential product candidate in 2024 |
| 11 • ©2024 EyePoint Pharmaceuticals,                                            | Inc. All Rights Reserved.   |                |              | ular degeneration; EOP2<br>eathy; DME, diabetic ma |         |                         | EYEPOINT PHARMACEUTICALS            |

TECHNOLOGY

## BIOERODIBLE DURASERT E™



### Safe, Sustained-Release IVT Drug Delivery

- Delivered via a standard in-office IVT injection
- Continuous, daily therapeutic dose
- Zero-order kinetics drug release

#### **Durasert E™: bioerodible**

- Drug embedded within a bioerodible matrix as a solid insert
- Designed to deplete drug load before matrix fully erodes
  - DURAVYU™

IVT, intravitreal

licensed to Alimera: 2 – licensed to Bausch and Lomb



## R&D Day: Agenda

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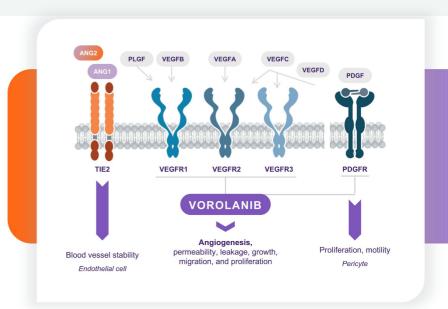


## DURAVYU entering Phase 3 with robust dataset and FDA alignment on approval pathway



## 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



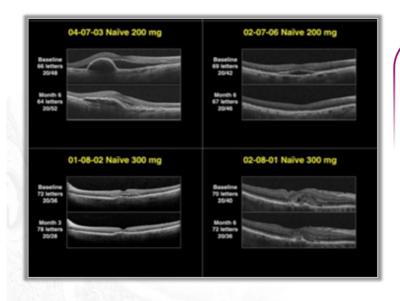
Sophie Bakri, M.D., et al. PLOS ONE.

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0304782, 2024.
VEGF(R), vascular endothelial growth factor (receptor); TKI, tyrosine kinase inhibitor;
PDGF(R), platelet-derived growth factor (receptor): TIE-2, tyrosine-protein kinase recet



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## Vorolanib Demonstrated Compelling Clinical Activity in wet AMD Delivered Orally

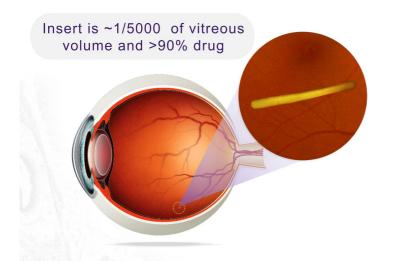


- Reduced supplemental therapy versus anti-VEGF PRN for all doses
- No ocular toxicity
- Systemic use significantly reduced fellow eye conversion
- Meaningful reduction in mean OCT thickness in treatment-naive patients

Timothy L. Jackson, PhD, FRCOphth, et al. Oral Tyrosine Kinase Inhibitor for Neovascular Age-Related Macular Degeneration, JAMAOphthalmology 2017.



### DURAVYU: Vorolanib in Bioerodible DurasertE™



- Immediately bioavailable
- Controlled release for at least six months enables redosing regimen
- No free-floating drug fully eluted prior to bioerosion of matrix
- Routine intravitreal injection
- Shipped and stored at ambient temperature

EYEPOINT'

## DURAVYU Demonstrated Clinically Meaningful Safety and Efficacy Outcomes Across Multiple Indications

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

| Trial   | n size | Indication | Safety                                     | Key Efficacy Outcomes                                                                                              |
|---------|--------|------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| DAVIO   | 17     | wet AMD    |                                            | Stable BCVA and OCT     74% reduction in treatment burden                                                          |
| DAVIO 2 | 161    | wet AMD    | Favorable safety profile                   | <ul><li>Statistically non-inferior BCVA</li><li>&gt;80% reduction in treatment burden</li><li>Stable OCT</li></ul> |
| PAVIA   | 77     | NPDR       | No DURAVYU related ocular or systemic SAEs | Stable to improved disease severity up to 9-<br>months; trial continuing 12 months                                 |
| VERONA  | 27     | DME        |                                            | Trial underway                                                                                                     |

Interim, masked safety as of June 2024
Wet AMD, wet age-related macular degeneration; NPDR, non-proliferative diabetic retinopathy;



## R&D Day: Agenda

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



- 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<sup>1</sup>



- Current "treat and extend" protocol still places significant burden on physicians and patients
  - Chronic disease treated with short acting anti-VEGF biologics



- A delay in care/missed visit can result in vision loss
  - A delay in treatment of only 5.34 weeks resulted in vision loss<sup>2</sup>

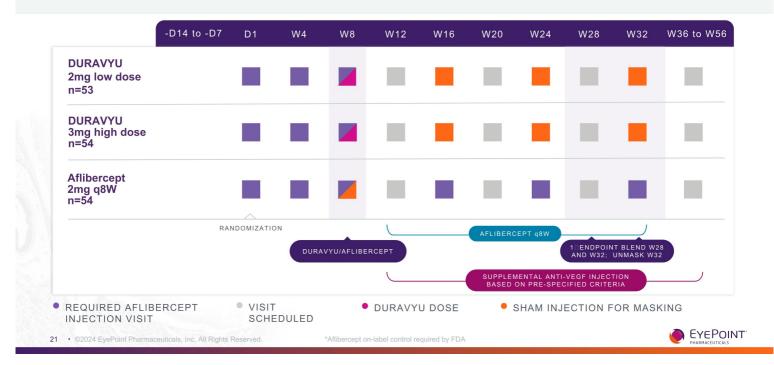


- An aging population means significantly more injections in a patient's lifetime
  - Current anti-VEGF treatments are dosed on average every two months in the United States<sup>3</sup>

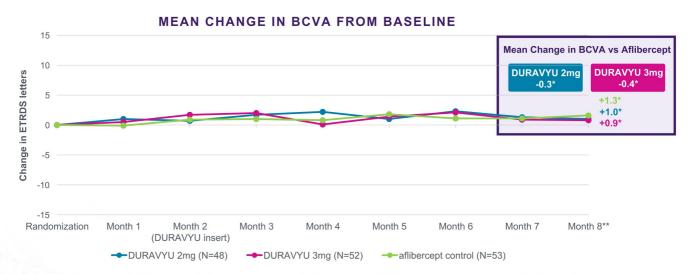
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1. 2022 PAT Survey; 2. American Academy of Ophthalmology, *The Effect of Delay in Care Among Patients Requiring Intravitreal Injections*, Welin Song, BS et al; 3. NIH *Current and Upcoming Anti-VEGF Therapies and Dosing Strategies for the treatment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

## 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)



In the Pulsar trial, HD Eylea (16-week 8mg arm) change in BCVA vs. 2mg Eylea was -1.4 letters1

CI, Confidence Interval
PRELIMINARY DATA – PENDING FINAL ANALYSIS



1 - AAO 2022 presentation, Paolo Lanzetta, on behalf of

## 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%         |

Normalized

PRELIMINARY DATA - PENDING FINAL ANALYSI



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

|                                                           | DURAVYU 2mg | DURAVYU 3mg | Aflibercept<br>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                     |

PRELIMINARY DATA – PENDING FINAL ANALYSIS

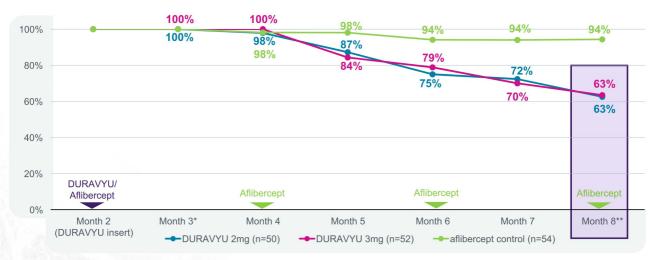
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## Nearly Two-Thirds of Eyes Treated with DURAVYU were Supplement-Free up to Six Months

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

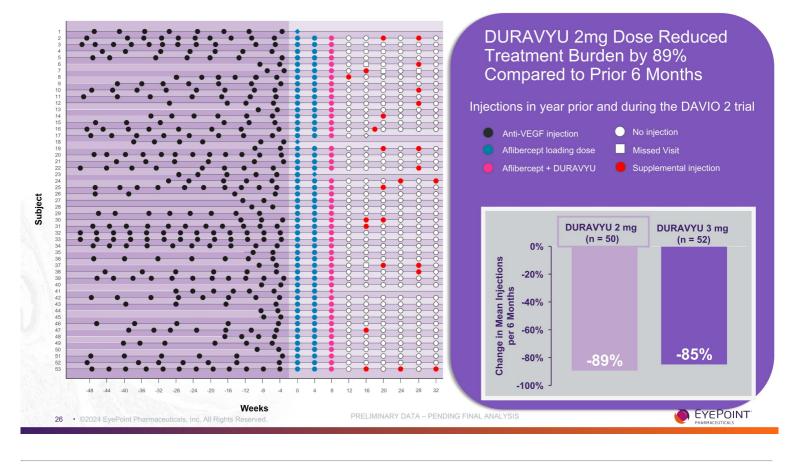
#### SUMMARY OF SUPPLEMENT-FREE RATES BY MONTH

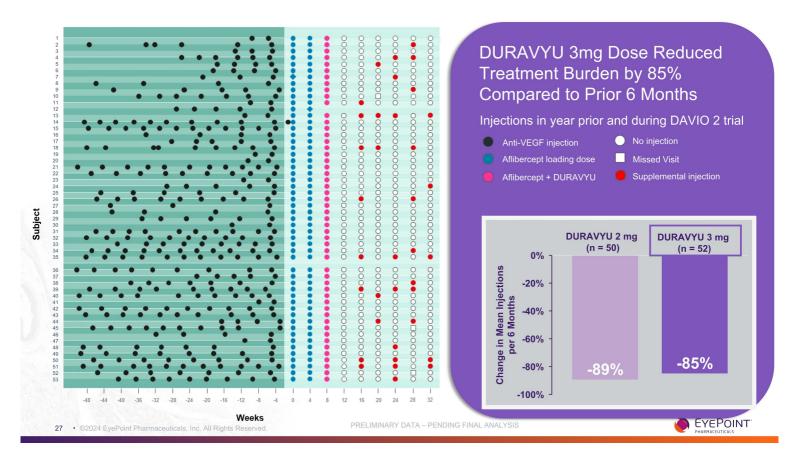


\*First visit patients are eligible to be supplemented EOM, every-other-month PRELIMINARY DATA – PENDING FINAL ANALYSIS

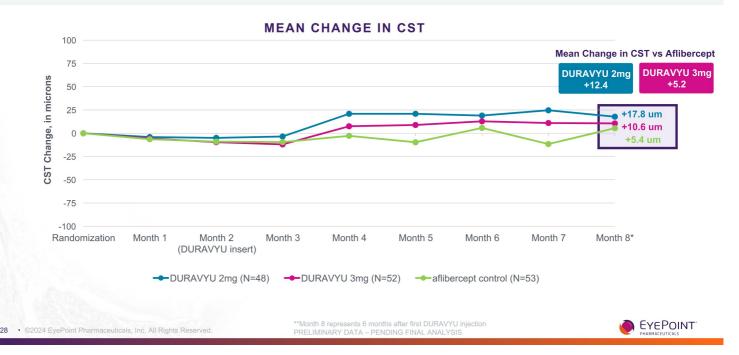


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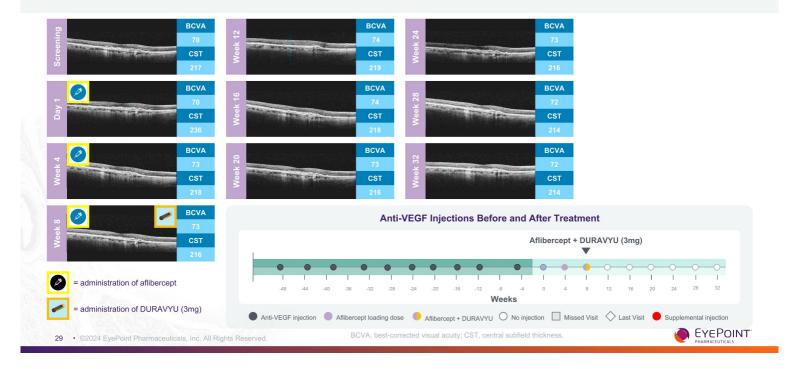




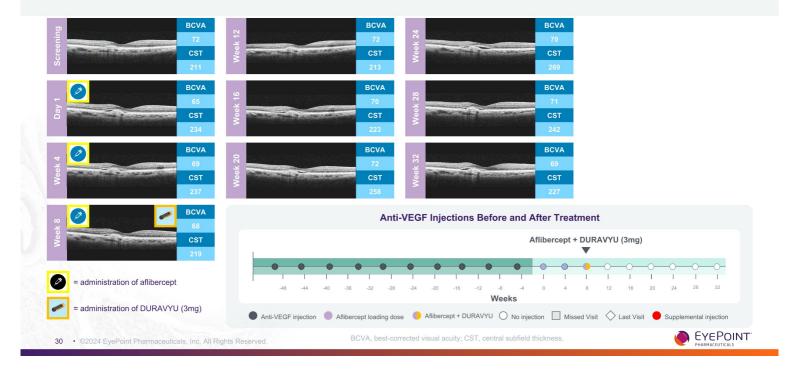
## Data from DAVIO 2 Suggests Strong Anatomic Control at 6-Months Compared to the Aflibercept Control



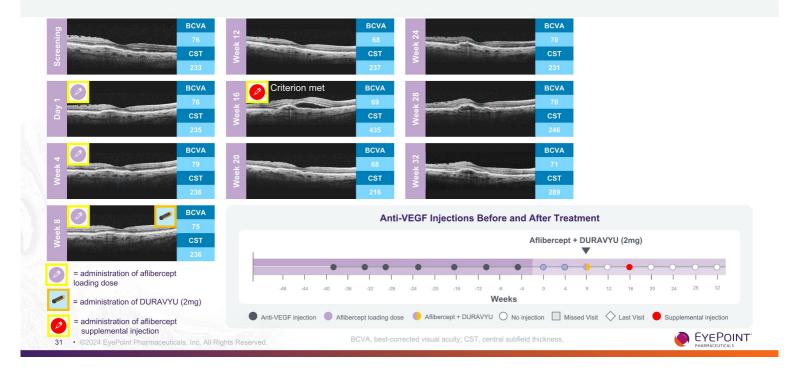
## DAVIO 2 Case Study: Patient with Frequent Anti-VEGF Injections Was Maintained for at Least Six Months After Receiving DURAVYU



## 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

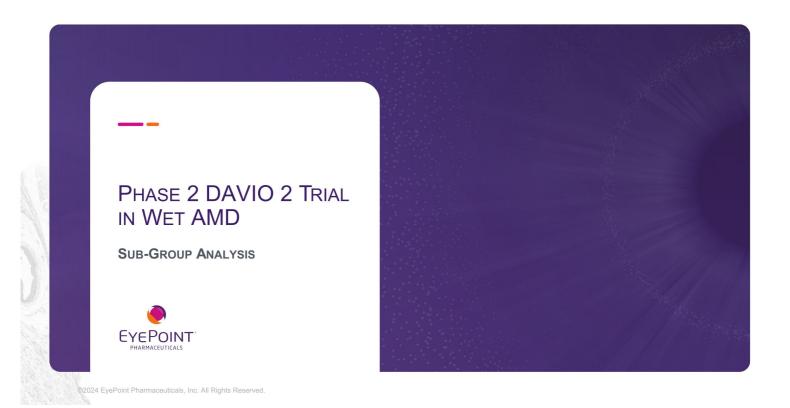


## DURAVYU Phase 2 DAVIO 2 Clinical Trial in Wet AMD Met All Primary and Secondary Endpoints

| Endpoint                                                    | 2mg                                                           | 3mg                                                           |  |
|-------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|--|
| Primary: Non-inferior change in BCVA vs. aflibercept        | - 0.3 letters                                                 | - 0.4 letters                                                 |  |
| Secondary: Favorable safety profile1                        | No DURAVYU-related SAEs                                       |                                                               |  |
| Secondary: Reduction in treatment<br>burden vs. 6 mos prior | 89%                                                           | 85%                                                           |  |
| Secondary: Reduction in treatment burden vs. aflibercept    | 83%                                                           | 78%                                                           |  |
| Secondary: Supplement-free up to 6 months                   | 63%<br>88% of eyes had 0 or only<br>1 supplemental injections | 63%<br>83% of eyes had 0 or only<br>1 supplemental injections |  |
| Secondary: Anatomical control vs.<br>aflibercept            | +12.4um                                                       | +5.2um                                                        |  |

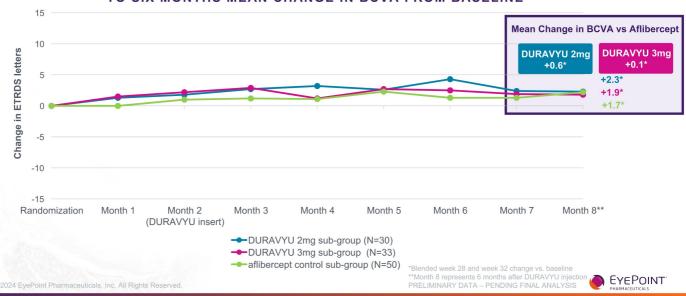
. As of June 14, 2024 data cut PRELIMINARY DATA – PENDING FINAL ANALYSIS





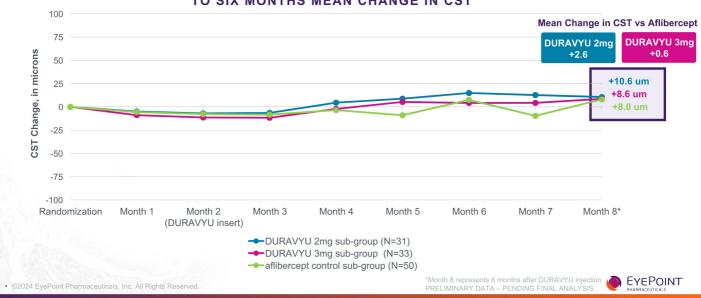
# Sub-Group Analysis of Supplement-Free Patients Demonstrated Eyes Treated with DURAVYU had Numerically Better Visual Acuity vs. Control

### SUB-GROUP ANALYSIS OF PATIENTS SUPPLEMENT-FREE UP TO SIX MONTHS MEAN CHANGE IN BCVA FROM BASELINE



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

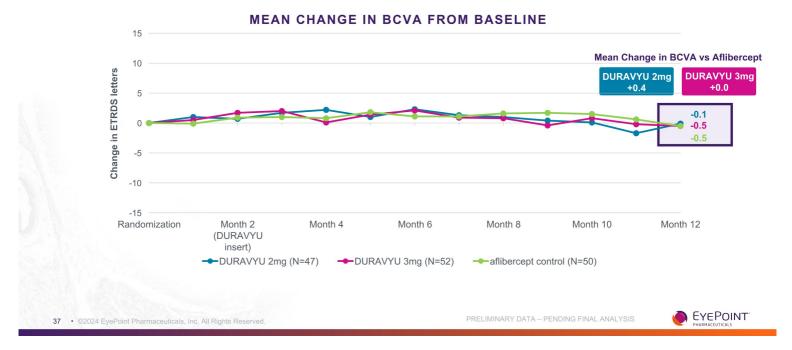




| Group Analyses  DURAVYU™: Phase 2 DAVIO 2 12-Month Topline Results | Carl D. Regillo, M.D. |
|--------------------------------------------------------------------|-----------------------|
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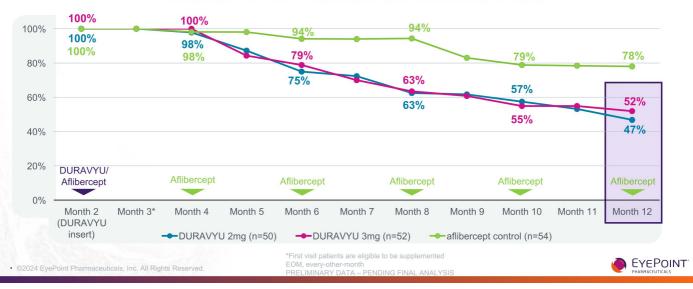
# Nearly Identical BCVA Compared to Aflibercept Through 12-Months After a Single Injection; Statistically Significant (95% CI)



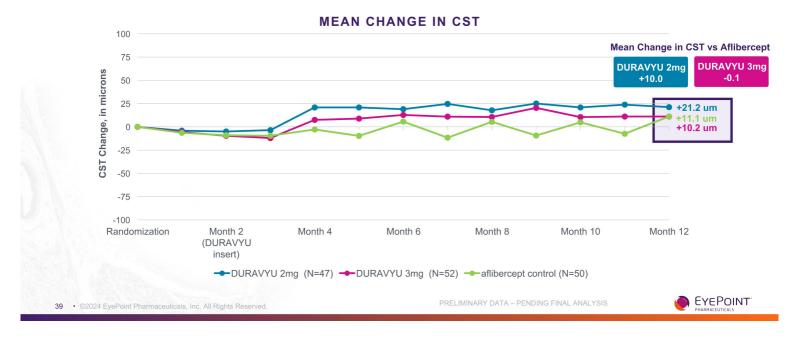
# Clinically Meaningful Supplement-Free Rates in DURAVYU Treated Eyes After Single Injection

DESPITE **EOM** AFLIBERCEPT INJECTIONS, 22% OF THE CONTROL GROUP REQUIRED ADDITIONAL SUPPLEMENTATION

#### SUMMARY OF SUPPLEMENT-FREE RATES BY MONTH



# 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

1. As deemed by the investigator Data as of June 14, 2024

SAE, serious adverse event; AE, adverse event; IVT, intravitreal injection PRELIMINARY DATA CUT- PENDING FINAL ANALYSIS



### 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.<br>Ramiro Ribeiro, M.D., Ph.D.                  |
|---------------------------------------------|-----------------------------------------------------------------|
| Early Pipeline                              | Jay Duker, M.D.                                                 |
| Key Opinion Leader Insights and Discussion  | Jay Duker, M.D.<br>Carl D. Regillo, M.D.<br>Yasha S. Modi, M.D. |
| Q&A                                         | All                                                             |
| Closing Remarks                             | Jay Duker, M.D.                                                 |



# Clear Regulatory Pathway for Phase 3 Pivotal Trials in wet AMD Informed by Multiple FDA Interactions

4Q
2022
Type C

Type C meeting to discuss pivotal trial design 4Q 2022

Received written FDA agreement on key trial design elements 3Q 2023

Initiated
DAVIO 2 trial
- design
informed by
Type C
meeting to
support future

pivotals

4Q

Positive DAVIO 2 data

2023

2Q 2024

Positive EOP2 meeting with FDA 2Q 2024

Received EOP2 meeting minutes substantiating pivotal trial design 2H 2024

Initiate Phase 3 program – LUGANO (US) and LUCIA (US/Ex-US) to follow



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

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

#### - OBJECTIVE -

Demonstrate DURAVYU, when administered every six months, achieves similar visual outcomes to on-label aflibercept while reducing treatment burden

#### DESIGN

- Two pivotal, non-inferiority trials
- ~400 patients per trial
- Two arms: 2.7mg DURAVYU vs. aflibercept control

#### **ENDPOINTS**

**Primary Endpoint:** difference in mean change in BCVA from Day 1 to Week 52 and 56 (blended) versus aflibercept control

**Secondary endpoints:** safety, reduction in treatment burden, percent of eyes supplement-free, anatomical stability

EYEPOINT

# Phase 3 Program is Designed to Drive Global Regulatory and Commercial Success

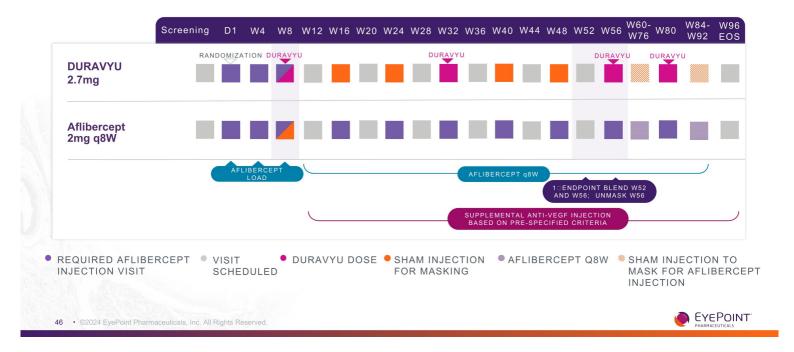
#### **KEY TRIAL DESIGN ELEMENTS -**

- 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

EYEPOINT

### 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

- ✓ Enriches trial to have more supplement-free eyes, which had better outcomes in DAVIO 2
- Ensures broad label and global reimbursement
- ✓ Speeds enrollment; >80 sites already selected
- ✓ Supports real-world clinical use for physicians and patients
- ✓ Three loading doses of aflibercept; all patients will be previously treated when receiving DURAVYU

EYEPOINT

# 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 <u>potential patient population</u> but also increases the probability of success

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



### **Commercial Manufacturing Facility**



New manufacturing site for clinical and commercial products



Conveniently located in Northbridge, MA, near EyePoint headquarters



Built to EYPT specifications with no capital investment required preserving cash



Built to US FDA and EU EMA standards



40,000 sqft cGMP manufacturing facility





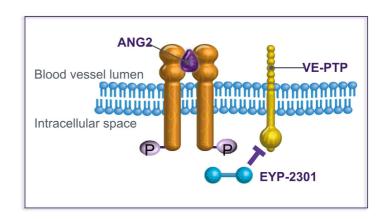
| DURAVYU™: Pivotal Phase 3 Plans for Wet AMD | Jay Duker, M.D.<br>Ramiro Ribeiro, M.D., Ph.D.                  |  |  |
|---------------------------------------------|-----------------------------------------------------------------|--|--|
| Early Pipeline                              | Jay Duker, M.D.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



# EYP-2301: Razuprotafib in Durasert E<sup>™</sup> 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 durability<sup>1</sup> of treatment
- Razuprotafib (f/k/a AKB-9778) delivered subcutaneously demonstrated preclinical and clinical proof of concept in posterior segment disease <sup>2,3</sup>



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



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



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



| Closing Remarks                            | Jay Duker, M.D.<br>Ramiro Ribeiro, M.D., Ph.D.                  |
|--------------------------------------------|-----------------------------------------------------------------|
| Q&A                                        | All                                                             |
| Key Opinion Leader Insights and Discussion | Jay Duker, M.D.<br>Carl D. Regillo, M.D.<br>Yasha S. Modi, M.D. |
| Early Pipeline                             | Jay Duker, M.D.                                                 |
| DURAVYU™: Pivotal Phase 3 Plans for Wet A  | 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                          | na DAVIO 2 sub-group analyses Topline DAVIO 2 12-month data                                                                         |                                                                                     |  |
| AAO                               | DAVIO 2 12-month sub-group analyses                                                                                                 | October 2024                                                                        |  |
| FloRetina                         | TBD                                                                                                                                 | December 2024                                                                       |  |
| Publications                      |                                                                                                                                     | Link                                                                                |  |
| in Patients With Wet Age-Relate   | Bioerodible, Sustained-Delivery Vorolanib Insert ed Macular Degeneration t al. <i>Ophthalmology Science</i> . 2024 Apr 8:4(5)       | https://www.ophthalmologyscience.or<br>g/article/S2666-9145(24)00063-<br>0/fulltext |  |
| growth factor receptor inhibitors | o: A comparative study of vascular endothelial<br>s and their anti-angiogenic effects<br>ks M, et al. <i>PLOS One</i> . 2024 June 4 | https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0304782           |  |



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

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FDA, Food and Drug Administration; SAE, serious adverse event; MOA, mechanism of action





UNIVERSITY CLUB | NEW YORK CITY | JUNE 26, 2024

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### EyePoint Pharmaceuticals to Highlight DURAVYU<sup>TM</sup> (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 -
    - EvePoint 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, DURAVYU<sup>TM</sup>(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 DURAVYU<sup>TM</sup> 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 non-inferiority 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 DURAVYU<sup>TM</sup> 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
  - o **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 DURAVYU<sup>TM</sup> 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 <a href="https://register.vevent.com/register/BI10e9bca3aca34595a46c9a0e08ef92da">https://register.vevent.com/register/BI10e9bca3aca34595a46c9a0e08ef92da</a>. A live webcast and subsequent archived replay of the presentation may be accessed via the Investors section of the Company website at <a href="https://www.eyepointpharma.com">www.eyepointpharma.com</a>. 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 DURAVYU<sup>TM</sup> 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

DURAVYU<sup>TM</sup>, 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<sup>™</sup> 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 E<sup>™</sup>technology for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU<sup>TM</sup> (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 E<sup>TM</sup>. Pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, formulated in Durasert E<sup>TM</sup> to potentially improve outcomes in serious retinal diseases. The proven Durasert<sup>®</sup> 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<sup>™</sup>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.



#### 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 EYP-1901 (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 (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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