



# EYEPOINT®

## **EyePoint Announces Positive Recommendation from Independent Data Safety Monitoring Committee for Pivotal Phase 3 Trials for DURAVYU™ in Wet Age-Related Macular Degeneration**

Nov 19, 2025

*– No changes in protocol recommended for LUGANO and LUCIA clinical trials –*

*– Masked safety data continues to show no safety signals, consistent with previous clinical trials for DURAVYU –*

*– On track to report topline 56-week data for LUGANO in mid-2026 with LUCIA data to closely follow –*

WATERTOWN, Mass., Nov. 19, 2025 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (Nasdaq: EYPT), a company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases, today announced that the independent Data Safety Monitoring Committee (DSMC) completed its second scheduled review of the Company's ongoing pivotal Phase 3 program evaluating DURAVYU for the treatment of wet age-related macular degeneration (wet AMD). As of the September 29, 2025 data cutoff for the DSMC review, all patients across the LUGANO and LUCIA trials reached the Week 8 visit during which patients in the DURAVYU arms received their initial DURAVYU dose, and approximately 25% of those patients received their second planned dose of DURAVYU at Week 32.

The DSMC recommended that both the LUGANO and LUCIA trials continue as planned, with no modifications to the protocol. The DSMC is an independent panel of experts in ophthalmology and biostatistics who are responsible for reviewing safety data to ensure the welfare of trial participants and to provide recommendations regarding trial conduct. DSMC meetings are scheduled to occur every six months per the trial protocol.

"We are pleased to receive our second consecutive positive recommendation from the DSMC for our pivotal wet AMD program. Now that all patients are past initial dosing and a growing number have received redosing, this recommendation strengthens our confidence in DURAVYU's consistent, favorable safety profile observed across its robust development history," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer at EyePoint. "As we advance toward topline data starting in mid-2026, we remain focused on continued clinical trial execution and regulatory preparedness to support our ultimate goal of delivering DURAVYU to patients as expeditiously as possible."

LUGANO and LUCIA are randomized, double-masked, aflibercept controlled, non-inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU in patients with active wet AMD including both treatment naïve and treatment experienced patients. Enrollment is complete in both trials with over 900 patients enrolled. At Day 1, patients are randomized 1:1 to receive either DURAVYU 2.7mg every six months or aflibercept on-label as control. The LUGANO and LUCIA trials are the only sustained release wet AMD pivotal Phase 3 trials evaluating 6-month redosing in both trials over two years. DURAVYU is delivered via a standard intravitreal injection in the physician's office, similar to current practice with FDA approved anti-VEGF treatments. The primary endpoint of the Phase 3 pivotal trials is non-inferiority in the average change in best corrected visual acuity (BCVA) at weeks 52 and 56 compared to baseline. Secondary endpoints include safety, reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections, and anatomical results as measured by optical coherence tomography (OCT). More information about the trial is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (LUGANO identifier: NCT06668064; LUCIA identifier: NCT06683742).

### **About Wet AMD**

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

### **About DURAVYU™**

DURAVYU™ (vorolanib intravitreal insert), is being developed as a potential sustained-delivery treatment for patients suffering from

serious retinal diseases. DURAVYU is a solid bioerodible insert designed to release a constant therapeutic dose for at least six months and is administered via a routine intravitreal injection with a sterile, prefilled syringe injector. DURAVYU combines vorolanib in next-generation Durasert E™ technology: Durasert E is EyePoint's proprietary and best-in-class bioerodible matrix designed to provide sustained release of drug without free-floating drug particles.

Vorolanib is a differentiated and patent-protected tyrosine kinase inhibitor (TKI) and is the most studied TKI in retinal disease, with no ocular safety signals noted in four prior trials. Vorolanib features a novel multi-mechanism of action as it targets both VEGF-mediated vascular permeability and IL-6 mediated inflammation through inhibition of all VEGF and JAK1 receptors. Vorolanib demonstrated neuroprotection in an in vivo model of retinal detachment and inhibits PDGF, which may bring antifibrotic benefits.

DURAVYU has safety and efficacy data across approximately 140 wet age-related macular degeneration and diabetic macular edema patients from both Phase 1 and 2 trials that demonstrate stability in vision and anatomical control. Data from the DAVIO 2 Phase 2 trial in wet AMD demonstrated an impressive 88% reduction in treatment burden six months after treatment with DURAVYU, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection. No safety signals have been observed in 190+ patients across four completed clinical trials, including three Phase 2 trials.

The wet AMD Phase 3 pivotal program (LUGANO and LUCIA) is evaluating every six-month dosing of DURAVYU, potentially providing a flexible label for physicians. The Phase 3 pivotal program follows a well-established regulatory approval pathway with a patient-centric non-inferiority design comparing DURAVYU to on-label standard of care to inform real-world treatment practices.

DURAVYU is also being advanced for the treatment of DME with first patient dosing in Phase 3 trials (COMO and CAPRI) expected in the first quarter of 2026. The Phase 2 VERONA trial in DME met primary and secondary endpoints and demonstrated a rapid and sustained improvement in vision and anatomy, and a continued favorable safety and tolerability profile with superior dosing intervals to standard of care.

## **About EyePoint**

EyePoint Pharmaceuticals, Inc. (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases. The Company's lead product candidate, DURAVYU™, is an innovative investigational sustained delivery treatment for serious retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor, in next-generation bioerodible Durasert E™ technology. Supported by robust safety and efficacy data across multiple clinical trials and indications, DURAVYU is currently being evaluated in Phase 3 pivotal trials for wet age-related macular degeneration with expected topline data beginning in mid-2026. First patient dosing in the pivotal Phase 3 clinical trials in diabetic macular edema is expected in the first quarter of 2026.

The Company is committed to partnering with the retina community to improve patient lives while creating long-term value, with four approved drugs over three decades and tens of thousands of eyes treated with EyePoint innovation.

EyePoint is headquartered in Watertown, Massachusetts, with a commercial manufacturing facility in Northbridge, Massachusetts.

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

*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.*

## **Forward Looking Statements**

EYEPOINT SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding our expectations regarding our clinical development and regulatory plans; our belief that DURAVYU™ is well-positioned to be the first-to-market among all investigational sustained release treatments for wet AMD; our belief that DURAVYU is the only TKI in development for DME; our belief that believe that DURAVYU is uniquely positioned to potentially address both VEGF-mediated vascular leakage and IL-6 mediated inflammatory drivers of DME as a sustained delivery therapy; our belief that DURAVYU's potential real-world application in multiple retinal disease indications and established trial designs position DURAVYU for clinical and commercial success; our expectations regarding timing for commencement of DME clinical trial enrollment and the timing of the availability and release of wet AMD clinical data; our expected cash runway; our belief that DURAVYU has the potential to maintain a majority of patients with active disease with no supplemental anti-VEGF therapy for six months or longer; and our expectations regarding the timing and clinical development of our other product candidates, including EYP-2301; and other statements regarding the Company's future plans, objectives, strategies and beliefs, as identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," or 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, these risks and uncertainties include the timing, progress and results of the Company's clinical

development activities, including DURAVYU; uncertainties and delays relating to communications with the U.S. Food and Drug Administration and the ability to obtain regulatory approval from FDA for the commercialization of DURAVYU; unanticipated costs and expenses; the Company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the risk that results of clinical trials may not be predictive of future results, and interim and preliminary data are subject to further analysis and may change as more data becomes available; unexpected safety or efficacy data observed during clinical trials; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for approval of the Company's product candidates; changes in the regulatory environment; disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA; changes in U.S. and international trade policies; changes in expected or existing competition; the success of current and future license agreements; our dependence on contract research organizations, and other outside vendors and service providers; product liability; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; delays, interruptions or failures in the manufacture and supply of our product candidates; the availability of and the need for additional financing; our ability to obtain additional funding to support our clinical development programs; uncertainties regarding the timing and results of the August 2022 subpoena from the U.S. Attorney's Office for the District of Massachusetts; uncertainties regarding the FDA warning letter pertaining to the Company's Watertown, MA manufacturing facility; 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. A more complete discussion of the risks and uncertainties that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, in our other filings with the Securities and Exchange Commission (SEC) and in our future reports to be filed with the SEC, which are available at [www.sec.gov](http://www.sec.gov). 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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