EyePoint Announces Third Consecutive Positive DSMC Recommendation for Phase 3 Wet AMD Trials for DURAVYU™, Building Confidence Ahead of Mid-2026 Topline Data

May 14, 2026

– LUGANO topline data on track for mid-2026, with LUCIA readout to follow shortly after –

– Continued favorable safety profile observed in masked Phase 3 DURAVYU data, consistent with four previously completed clinical trials –

– All active patients in the treatment arm have reached their second DURAVYU dosing visit, with over 35% receiving a third dose –

WATERTOWN, Mass., May 14, 2026 (GLOBE NEWSWIRE) -- EyePoint, 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 third scheduled review of the Company's pivotal Phase 3 program evaluating DURAVYU for wet age-related macular degeneration (wet AMD) and recommended that both the LUGANO and LUCIA trials continue as planned with no protocol modifications. As of May 2, 2026, all active patients in the treatment arm have reached the Week 32 visit, during which patients received their second DURAVYU dose. Over 35% of those patients have also received their third planned dose at Week 56.

Interim masked safety data from the Phase 3 trials show a continued favorable safety profile for DURAVYU, consistent with the safety observed in over 190 patients across four completed clinical trials. 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, and this is the last anticipated DSMC meeting ahead of topline data.

"Safety is paramount in retinal disease therapies, and receiving three consecutive positive DSMC recommendations to continue our Phase 3 wet AMD trials without modification reflects the consistency of DURAVYU's safety profile and the rigor of our Phase 3 wet AMD program design," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer at EyePoint. "This continued independent validation, together with the favorable safety profile observed across four completed clinical trials, reinforces our confidence as we approach Phase 3 topline data beginning in mid-2026. If successful, we believe that DURAVYU is well-positioned to be a first and best-in-class therapy with the potential to establish a new treatment paradigm for patients who have long needed better options."

LUGANO and LUCIA are identical, 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 on-label aflibercept as control. All active patients in the treatment arm have reached the Week 32 visit, during which patients received their second DURAVYU dose. 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 (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 an investigational sustained-delivery treatment for patients suffering from serious retinal diseases. DURAVYU combines vorolanib, a selective and patent-protected tyrosine kinase inhibitor (TKI), in next-generation bioerodible Durasert E ™, a proprietary and best-in-class IVT delivery technology designed to provide sustained release of drug for at least six months without free-floating drug particles.

DURAVYU brings a potential new multi-mechanism of action and treatment paradigm for retinal diseases beyond existing anti-VEGF large molecule ligand blocking therapies, as vorolanib acts intracellularly to suppress angiogenesis through the inhibition of all VEGF receptors and PDGFR, while also suppressing inflammation through the inhibition of interleukin 6 (IL-6)/JAK1 signaling. In addition to the safety and efficacy demonstrated in the DAVIO, DAVIO 2 and VERONA clinical trials, vorolanib has also demonstrated neuroprotection in an in-vivo model of retinal detachment.

DURAVYU has established safety and efficacy data from both Phase 1 and 2 trials in wet AMD and DME that demonstrate stability in vision and anatomical control with a single dose of DURAVYU. No drug-related safety concerns were observed in over 190 patients across four completed clinical trials, including three Phase 2 trials.

Informed by the robust Phase 2, DAVIO trial, which achieved statistically positive and clinically meaningful results vs. on-label aflibercept, the fully enrolled wet AMD Phase 3 pivotal program (LUGANO and LUCIA) is the only investigational program evaluating every six-month dosing of DURAVYU, which enables the potential to support a compelling competitive label and advantage for DURAVYU. With over 900 patients randomized across both trials, the Phase 3 pivotal program follows a well-established regulatory approval pathway with a patient-centric noninferiority design comparing DURAVYU to on-label standard of care to inform real-word treatment practices. Data from the Phase 3 program are anticipated to be reported beginning in mid-2026.

DURAVYU is also being evaluated for the treatment of DME, with both Phase 3 trials (COMO and CAPRI) underway and actively recruiting patients. 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. Data from the Phase 3 program is anticipated to be reported in the second half of 2027.

About EyePoint

EyePoint, 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 (wet AMD) and diabetic macular edema (DME). Topline data is expected for wet AMD beginning in mid-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 Betta 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 the two largest retinal disease markets, wet AMD and DME; our belief that DURAVYU is the only TKI in development for DME; our belief 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 the timing of the availability and release of wet AMD and DME clinical data; our financial position and 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; our beliefs regarding the potential market opportunity for DURAVYU in wet AMD and DME; our ability to continue to scale operations at our commercial manufacturing facility in Northbridge, Massachusetts; our expectations that our manufacturing facility will continue to meet FDA and EMA standards and support commercialization efforts of DURAVYU upon regulatory approval; and our

expectations regarding the timing and clinical development of our other product candidates; 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; 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; 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, including due to unanticipated regulatory compliance issues or warning letters relating to the Company's manufacturing facilities; the availability of and the need for additional financing; our ability to obtain additional funding to support our clinical development programs; our ability to enter into a settlement agreement and corporate integrity agreement with the government regarding the DOJ investigation and uncertainties related to the impact such agreements would have on our business, financial condition and operations; 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. 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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