EyePoint Completes Enrollment of Both Pivotal Phase 3 Trials of DURAVYU ™ for Treatment of Diabetic Macular Edema (DME)

Jul 30, 2026

– COMO and CAPRI trials together rapidly enrolled over 480 participants in five months, demonstrating continued enthusiasm for DURAVYU trial participation among retinal specialists and patients —

– Topline 56-week data for both DME trials anticipated in 4Q 2027 –

WATERTOWN, Mass., July 30, 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 it has completed enrollment in COMO and CAPRI, the two global Phase 3 clinical trials of DURAVYU ™ (vorolanib intravitreal insert) for the treatment of diabetic macular edema (DME). Over 480 patients have been enrolled across both trials, with full enrollment occurring ahead of schedule, in only five months. Topline data for both DME trials are anticipated in the fourth quarter of 2027.

“Completing enrollment across both COMO and CAPRI ahead of expectations is a testament to our team's exceptional execution and dedication to delivering a potentially more durable and differentiated treatment option for patients with DME, the second largest retinal disease market," said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. "DURAVYU's compelling efficacy and safety profile, combined with positive feedback on our trial design from both the FDA and EMA, underscores our confidence in the program as we advance toward topline data in DME anticipated next year.”

COMO and CAPRI are global, randomized, double-masked, on-label 2mg aflibercept controlled non-inferiority Phase 3 trials assessing the safety and efficacy of DURAVYU in DME, and include both treatment-naïve and previously treated patients. Patients are randomized on Day 1 to a DURAVYU 2.7mg dose arm or the aflibercept control arm. Patients in the DURAVYU arm will be re-dosed every six months. DURAVYU is delivered via a single standard intravitreal injection in the physician's office, similar to current FDA approved intravitreal treatments. The primary endpoint is a non-inferior change from baseline in best corrected visual acuity (BCVA) to weeks 52 and 56, blended, compared to on-label 2mg aflibercept control. Secondary endpoints include safety, superiority in reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections, and anatomical results as measured by optical coherence tomography (OCT).

“Today’s milestone represents an important advancement for the retina community, as DME patients remain chronically undertreated given the current frequent and burdensome injection schedule,” said Veeral Sheth, M.D., Partner and Director of Clinical Research at University Retina and Macula Associates. “The early and sustained visual and anatomical improvements and encouraging safety profile demonstrated by DURAVYU in the Phase 2 VERONA trial, alongside the Phase 2 DAVIO 2 trial in wet AMD, provide a strong foundation for these Phase 3 studies. The rapid enrollment of COMO and CAPRI highlights the excitement in the community to potentially utilize DURAVYU’s sustained drug delivery and multi-mechanism of action, which targets inflammation through the inhibition of IL-6/JAK1 signaling alongside the blocking of all VEGF receptors, to provide more durable outcomes for DME patients.”

In May 2026, an independent Data Safety Monitoring Committee (“DSMC”) convened to review masked safety data from DURAVYU’s ongoing Phase 3 programs in wet age-related macular degeneration (wet AMD) and DME. Upon completion of its review, the DSMC recommended continuation of both programs as planned, with no protocol modifications. DURAVYU has been evaluated in over 190 patients across four completed clinical trials, demonstrating a favorable safety and tolerability profile including no observed DURAVYU-related safety concerns.

The pivotal Phase 3 COMO and CAPRI trials were informed by the safety and efficacy findings from the VERONA Phase 2 clinical trial in which DURAVYU 2.7mg demonstrated an early and sustained improvement in BCVA, reduction in treatment burden of two-thirds, extended time to first supplemental injection versus aflibercept control, and anatomical improvements in central subfield thickness (CST). The Phase 3 program has been developed in alignment with both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Leveraging the established investigator network from the pivotal wet AMD program, many clinical trial sites from the wet AMD program are participating in the pivotal DME program, reflecting strong medical community engagement and enthusiasm across the Company’s clinical trials and programs.

About Diabetic Macular Edema

Diabetic macular edema (DME) is the leading cause of vision loss in people with type 1 and type 2 diabetes. DME results when

damaged blood vessels leak fluid into the macula, the central portion of the retina responsible for the sharp vision needed for routine tasks such as driving or reading. Evidence suggests DME is driven by not only VEGF, but also PDGF production as well as inflammation associated with interleukin-6 (IL-6) signaling. The resulting retinal swelling can cause blurred vision and may lead to severe vision loss or even legal blindness. DME is a common form of sight-threatening retinopathy in people with diabetes, with approximately 28 million people afflicted worldwide. As the prevalence of diabetes continues to grow, an increased number of people will be affected by diabetic eye diseases such as DME. The current standard of care for patients experiencing DME includes intravitreal injections of short-acting anti-VEGF biologics, corticosteroids, or laser photocoagulation which can become a burden on patients, caregivers, and physicians due to the longevity of the disease.

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 safety signals 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 wet AMD program are anticipated to be reported beginning in August 2026.

DURAVYU is also being evaluated for the treatment of DME, with both Phase 3 trials (COMO and CAPRI) fully enrolled and underway. 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. Pivotal data from the Phase 3 DME program is anticipated to be reported in the fourth quarter 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 August 2026 and for DME in the fourth quarter of 2027.

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; 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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