EyePoint Announces First Patients Dosed in Both Global Phase 3 Clinical Trials of DURAVYU™ for the Treatment of Diabetic Macular Edema

Mar 2, 2026

– Active Phase 3 programs for DURAVYU in wet AMD and DME, the two largest multi-billion-dollar retinal disease markets –

– Topline data for DURAVYU in DME anticipated in 2H 2027 –

WATERTOWN, Mass., March 02, 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 the first patient dosed in both Phase 3 COMO and CAPRI global clinical trials of DURAVYU ™ (vorolanib intravitreal insert) for the treatment of diabetic macular edema (DME). DURAVYU is an investigational sustained delivery therapy delivering vorolanib, a selective tyrosine kinase inhibitor (TKI) that brings a novel, multi-mechanism of action inhibiting VEGF-mediated vascular permeability, PDGF, and IL-6 mediated inflammation to the potential treatment of DME.

“Dosing of the first patients in our two pivotal DME trials represents a significant milestone for EyePoint and DURAVYU – the only TKI in Phase 3 clinical trials for DME – and solidifies our leadership in sustained-release ocular drug delivery,” said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint. “Informed by the positive Phase 2 VERONA DME results, the efficient trial design of COMO and CAPRI follow an established non-inferiority regulatory pathway leveraging the relationships and infrastructure of our exceptionally well-executed pivotal wet AMD program. Together, these trials are designed to position DURAVYU with the potential to be the first-in-class and best-in-class TKI for DME, a disease that continues to cause vision loss and significant treatment burden despite available anti-VEGF therapies.”

“There is a clear need for more durable and differentiated treatment options for patients with DME,” said David Eichenbaum, M.D., Principal Investigator in the CAPRI clinical trial and Director of Research for Retina Vitreous Associates. “The current standard of care is overly burdensome for a largely working-age population, and existing therapies do not fully address the underlying disease, as up to two-thirds of DME patients still have active disease after anti-VEGF loading. DURAVYU’s multi-MOA uniquely targets inflammation through inhibition of IL-6/JAK1 signaling while also reducing vascular leakage through blocking of all VEGF receptors, as indicated by the early and sustained visual and anatomical improvements in the VERONA trial. In addition, DURAVYU is designed to provide consistent dosing for at least six months, potentially helping to protect vision between visits. We are excited to participate in the Phase 3 program as this marks an important and needed milestone for the retinal community.”

The DURAVYU DME program consists of two global, randomized, double-masked, on-label aflibercept controlled non-inferiority trials (COMO and CAPRI) assessing the safety and efficacy of DURAVYU in patients with DME, including both treatment-naïve and previously treated patients. Each trial will enroll approximately 240 patients, who are randomly assigned, on Day 1, to a DURAVYU 2.7mg dose arm or the aflibercept control arm. Patients in the DURAVYU 2.7mg arm will be re-dosed every six months, starting on Day 1 of the trial. DURAVYU 2.7mg is delivered via a single standard intravitreal injection in the physician's office, similar to current standard practice with 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 versus 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). The DME pivotal program was informed by a positive End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and has alignment with both the FDA and the European Medicines Agency (EMA).

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. DME is driven by VEGF and PDGF production and inflammation associated with interleukin-6 (IL-6) signaling. This resulting retinal swelling can cause blurred vision and may lead to severe vision loss or even 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 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 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 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. 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.

Investors:

Tanner Kaufman / Jenni Lu
FTI Consulting
Direct: 203-722-8743 / 667-321-6018
tanner.kaufman@fticonsulting.com / jenni.lu@fticonsulting.com

Media Contact:

Green Room Communications
Direct: 850-384-2833
EyePointMedia@grcomms.com

Source: EyePoint, Inc.