# EyePoint Announces Pivotal Phase 3 Program Initiation for DURAVYU™ in Diabetic Macular Edema

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*– DURAVYU now in Phase 3 for the two largest, multi-billion-dollar retinal disease markets, wet AMD and DME with first patient dosing in pivotal Phase 3 DME trials anticipated in Q1 2026 –*

*– New preclinical data demonstrates that vorolanib, the active drug in DURAVYU, inhibits both VEGF-mediated vascular permeability and IL-6 mediated inflammation, key contributors to wet AMD and DME –*

*– IL-6 finding supports the compelling efficacy data observed in the Phase 2 VERONA DME trial and underscores DURAVYU as a potential 6-month treatment –*

WATERTOWN, Mass., Oct. 14, 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 details for its pivotal Phase 3 program evaluating DURAVYU™ (vorolanib intravitreal insert) for the treatment of diabetic macular edema (DME) with first patient dosing anticipated in first quarter of 2026. The Company also shared new preclinical data that demonstrates vorolanib, the active drug in DURAVYU, inhibits interleukin-6 (IL-6) mediated inflammation through inhibition of all Janus Kinase (JAK) receptors, in particular JAK-1, in addition to known blockage of vascular endothelial growth factor (VEGF) mediated vascular permeability. This finding reinforces the early and sustained improvements observed through six months in the Phase 2 VERONA clinical trial and positions DURAVYU as a potential multi-mechanism of action (MOA) treatment.

“Following a positive end of Phase 2 meeting with the FDA, we are pleased to announce the initiation of our Phase 3 pivotal trials for DME, following an established non-inferiority approval pathway for this important indication,” said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer at EyePoint. “Despite available anti-VEGF therapies, many DME patients continue to lose vision, underscoring the need for a sustained delivery option that also addresses inflammation. Our new preclinical data demonstrates that in addition to the known blockage of VEGF, DURAVYU also blocks IL-6 mediated inflammation via inhibition of the JAK receptors, particularly JAK-1, making DURAVYU a potential multi-MOA option for physicians and patients. Our Phase 3 pivotal program preparations are well underway, and we anticipate dosing our first patient in the first quarter of 2026 positioning DURAVYU to be the first TKI to market in two significant indications.”

**DURAVYU Phase 3 DME Clinical Program Overview**

- U.S. Food and Drug Administration (FDA) alignment on approval pathway in DME consisting of two identical non-inferiority trials (“COMO” and “CAPRI”). The trials will include redosing of DURAVYU every six months.
- Each trial will enroll approximately 240 patients, including both previously treated and treatment naïve patients, who will be randomly assigned to either a DURAVYU 2.7mg arm or an on-label 2mg aflibercept control arm. Randomization occurs on Day 1.
- The primary endpoint is the change from baseline in best corrected visual acuity (BCVA) to weeks 52 and 56, blended, compared to on-label 2mg aflibercept.

**Data Supporting DURAVYU™ for the Treatment of DME**

New data demonstrates that DURAVYU has the potential to be a multi-MOA treatment, inhibiting both VEGF via inhibition of all VEGFRs and IL-6 signaling via JAK receptor blockage. IL-6 is a pro-inflammatory cytokine that has been observed at significantly higher levels in patients with DME and wet AMD compared to healthy individuals. IL-6 signaling occurs via activation of the JAK kinases, particularly JAK-1, leading to vascular leakage and inflammation that together compound damage to the blood-retinal barrier in DME.

There remains a clear need for treatment options that address both the VEGF-mediated vascular leakage and inflammation drivers of this disease, as well as treatment burden. Up to two-thirds of patients still have active DME after anti-VEGF loading, underscoring the multifactorial nature of the disease and suboptimal efficacy associated with a single-mechanism approach.

Vorolanib is a potent and selective tyrosine kinase inhibitor (TKI) that inhibits all VEGF and JAK receptors, particularly JAK-1, with new *in vitro* data showing a reduction in IL-6 activity of more than 50% potentially bringing a synergistic anti-inflammatory effect in addition to established VEGF inhibition. Furthermore, DURAVYU features sustained drug delivery providing consistent daily dosing

with receptor inhibition for at least six months after a single injection. The positive efficacy results from the Phase 2 VERONA trial, where a single DURAVYU 2.7mg dose demonstrated early and meaningful improvements in vision and anatomy compared to aflibercept, further underscore the potential clinical utility in DME.

“DME remains chronically undertreated, with patients experiencing persistent disease despite receiving standard of care anti-VEGFs,” said Roger A. Goldberg, MD, MBA, Vitreoretinal Surgeon at Bay Area Retina Associates; Co-Founder, Emmetrope Ophthalmics, LLC. “We know that inflammation plays a critical role in the pathogenesis of DME, and there is an urgent need for new treatment options that address the multifactorial nature of this disease while reducing the high treatment burden associated with existing therapies. I am thrilled that DURAVYU—the only TKI in development for center involving DME—plans to advance to a registrational program. Following the promising VERONA data, in particular the early and sustained visual acuity improvements with a superior dosing interval versus aflibercept and continued favorable safety profile, the retinal community is enthusiastic to see this program move forward in DME, and for the possibility of achieving better outcomes for our patients.”

The Company will be presenting the preclinical data on JAK/IL-6 inhibition at the Eyecelerator meeting at AAO 2025.

**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 both VEGF 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 being developed as a potential sustained-delivery treatment for patients suffering from serious retinal diseases. It is designed for intravitreal dosing in a pre-loaded syringe injector to deliver a consistent therapeutic dose for at least six months. DURAVYU combines vorolanib in next-generation Durasert E™ technology: Durasert E is EyePoint’s proprietary and best-in-class bioerodible sustained release insert with a matrix designed for sustained release of drug while prevent free-floating drug particles. DURAVYU contains no PEG or PLGA.

Vorolanib is a differentiated and patent-protected tyrosine kinase inhibitor and is the most studied TKI in retinal disease, with proven ocular safety. Vorolanib targets both VEGF-mediated vascular permeability and IL-6 mediated inflammation through inhibition of all VEGF and JAK receptors bringing a novel, multi-mechanism of action for retinal disease. Vorolanib has also demonstrated neuroprotection in an in vivo model of retinal detachment and inhibits PDGF, which may have antifibrotic benefits.

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

The wet AMD Phase 3 pivotal program (LUGANO and LUCIA) is evaluating every six-month re-dosing of DURAVYU allowing for 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-word treatment practices.

DURAVYU is also currently being evaluated for the treatment of diabetic macular edema (DME) with first patient dosing in Phase 3 trials expected in Q1 2026. The Phase 2 VERONA trial in DME met primary and secondary endpoints and demonstrated a rapid and sustained improvement in vision and anatomy, 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 (TKI), 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 two Phase 3 pivotal trials for wet age-related macular degeneration (wet AMD) with data anticipated in mid-2026. First patient dosing in the pivotal Phase 3 clinical trials in diabetic macular edema (DME) 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 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 of DURAVYU; our expectations regarding timing for the completion of clinical trial enrollment and the timing of the availability and release of clinical data; our optimism that DURAVYU has the potential to improve patient outcomes; our expectations regarding clinical development of our other product candidates, our business strategies and objectives; 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; the impact of the government shutdown on our business operations; 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; the Company's ability to obtain additional funding to support its 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.

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