



EyePoint Announces Topline Results from LUCIA, the Second Pivotal Phase 3 Clinical Trial of DURAVYU™ in Wet AMD

Oct 19, 2026

- LUCIA did not achieve the primary endpoint of statistical non-inferiority in mean change in BCVA versus on-label aflibercept control, despite demonstrating visual improvement –*
- Key secondary endpoints in LUCIA were met including a superior 38% reduction in treatment burden (nominal p-value <0.0001), with 52% of eyes supplement-free and 71% receiving zero or one supplement up to Week 56, as well as strong anatomic control –*
- Continued favorable safety profile for DURAVYU with redosing –*
- DME program remains on track with pivotal Phase 3 topline data from two identical clinical trials anticipated in Q4 2027 –*
- Conference call to discuss the results to be held today at 8:00 a.m. EDT –*

WATERTOWN, Mass., Oct. 19, 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 topline results from LUCIA, the second pivotal Phase 3 clinical trial of DURAVYU™ (vorolanib intravitreal insert) for the treatment of wet age-related macular degeneration (wet AMD).

In LUCIA, despite demonstrating visual improvement, DURAVYU did not achieve the primary endpoint of statistical non-inferiority in mean change in best corrected visual acuity (BCVA) versus on-label 2 mg aflibercept control. DURAVYU achieved key secondary endpoints including a continued favorable safety profile with redosing, along with a meaningful reduction in treatment burden, durability as demonstrated by supplement-free rates, and strong anatomic control at Week 56, consistent with the first Phase 3 LUGANO clinical trial. EyePoint will complete additional analyses of the LUCIA and pooled Phase 3 datasets to further assess next steps for DURAVYU as a potential treatment for wet AMD.

"We are disappointed that the LUCIA trial did not meet the primary endpoint given the promising scientific rationale of DURAVYU and its potential to improve outcomes for patients with wet AMD. We sincerely thank the patients, caregivers, clinicians and study teams who participated," said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. "Both LUCIA and LUGANO demonstrated DURAVYU's ability to control fluid and reduce the treatment burden for patients with wet AMD. These findings support DURAVYU's therapeutic potential in DME. With the multifactorial and inflammatory nature of DME, as well as compelling results in the Phase 2 VERONA trial, we believe DURAVYU is well positioned to potentially deliver stable vision with fewer injections than standard of care. We remain focused on executing on our Phase 3 DME program and continue to be guided by our unwavering mission of serving the retinal disease community."

LUCIA enrolled 475 patients and LUGANO enrolled 432 patients. Both trials randomized patients 1:1 to DURAVYU 2.7 mg every 24 weeks or on-label aflibercept 2 mg every eight weeks, with supplemental aflibercept as needed according to pre-specified criteria. LUGANO also did not meet the primary endpoint in its full dataset, despite demonstrating visual improvement. In LUGANO, DURAVYU also demonstrated strong and consistent performance across key secondary endpoints, including a 42% reduction in treatment burden (nominal p-value <0.0001), a favorable safety profile with redosing, durable supplement-free rates and strong anatomic control through Week 56.

"We are encouraged that more than 50% of DURAVYU patients remained supplement-free up to 56 weeks in both Phase 3 trials, providing further evidence of DURAVYU's durability in retinal disease," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint. "We remain confident in the DME program, supported by DURAVYU's biologic activity through inhibition of VEGF and the IL-6/JAK1 pathway, its continued favorable safety profile, and the early visual and anatomic improvements observed in VERONA."

The Phase 2 VERONA clinical trial in DME met its primary endpoint with extended time to first supplemental injection compared to aflibercept control for both DURAVYU doses. The trial also produced clinically meaningful outcomes, including a favorable safety profile with no DURAVYU-related ocular or systemic serious adverse events (SAEs) and an early and sustained improvement in vision and anatomical control. DURAVYU 2.7mg demonstrated a +7.1 letter BCVA gain and 76-micron central subfield thickness (CST) reduction at Week 24, with a supplement-free rate of 73% versus 50% for patients in the control arm. The Company continues to advance the ongoing pivotal COMO and CAPRI clinical trials, with topline data expected in the fourth quarter of 2027.

Conference Call Information

EyePoint management will host a conference call today, October 19, 2026, at 8:00 a.m. EDT to discuss the LUCIA topline results.

To access the live conference call and webcast, please register via the Events & Presentations page of the Investors section on the Company website at <https://investors.eyepoint.bio/events-and-presentations/events>. A webcast replay and the data presentation will also be available on the corporate website after the conference call.

About the Phase 3 Wet AMD Program

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. More than 900 patients were enrolled across the two trials.

Patients were randomized 1:1 to receive either DURAVYU 2.7 mg every six months or on-label aflibercept every 8 weeks as control, after 3 monthly loading doses. DURAVYU is administered via a standard intravitreal injection in the physician's office, consistent with current retinal treatment practice with FDA-approved anti-VEGF treatments. The primary endpoint is non-inferiority in the average change from baseline in best-corrected visual acuity (BCVA) at the blended Weeks 52 and 56. Secondary endpoints include safety, reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections, and anatomical outcomes as measured by optical coherence tomography (OCT). More information is available at www.clinicaltrials.gov (LUGANO: NCT06668064; LUCIA: 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 beneath the retina and leak blood or fluid, which can damage the macula and impair central vision.

Wet AMD is a lifelong disease requiring ongoing treatment to maintain visual function. Despite advances in treatments, frequent intravitreal injections remain a significant burden for patients, caregivers, physicians and the health care system, potentially leading to patient noncompliance and further vision loss. Current anti-VEGF therapies also primarily target extracellular VEGF signaling. There remains a need for durable therapies that can provide disease control while reducing treatment burden.

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), with EyePoint's proprietary next-generation bioerodible Durasert E™, a best-in-class intravitreal delivery technology designed to deliver 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, vorolanib has demonstrated neuroprotective activity in an *in vivo* model of retinal detachment.

DURAVYU has been evaluated across multiple clinical trials in wet AMD and DME, including the Phase 2 DAVIO 2 and Phase 3 LUGANO and LUCIA trials in wet AMD and Phase 2 VERONA trial in DME, and is in ongoing Phase 3 COMO and CAPRI trials in DME. No drug-related safety concerns were observed in over 630 patients across six completed clinical trials, including three Phase 2 trials and 2 Phase 3 trials.

The Phase 2 VERONA trial in DME met the 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, with EyePoint's proprietary bioerodible Durasert E™ sustained-delivery technology. DURAVYU is currently being evaluated in Phase 3 pivotal trials for diabetic macular edema (DME).

The Company is committed to partnering with the retinal 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 plans to complete additional analyses of the LUCIA and pooled Phase 3 datasets to further assess next steps for DURAVYU as a potential treatment for wet AMD; our expectations regarding DURAVYU's potential to improve treatment outcomes for patients with wet AMD; our belief that the LUCIA and LUGANO findings support DURAVYU's therapeutic potential in DME; our belief that DURAVYU brings a potential new multi-mechanism of action and treatment paradigm for retinal diseases beyond existing anti-VEGF large molecule ligand blocking therapies; our belief that DURAVYU is positioned well to potentially deliver stable vision with fewer injections than standard of care; our expectations regarding the timing of the availability and release of DME clinical data, including topline results for Phase 3 COMO and CAPRI clinical trials in DME in the fourth quarter of 2027; our belief that DURAVYU has the potential to maintain patients with active disease with no supplemental anti-VEGF therapy for six months or longer; 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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