EyePoint Announces Topline Data from LUGANO, the First of Two Pivotal Phase 3 Clinical Trials for DURAVYU™ 2.7mg in Wet AMD

Aug 17, 2026

– DURAVYU was non-inferior to on-label aflibercept control (nominal p-value = 0.0096) in an ad hoc analysis excluding a 4% asymmetric cohort (9 of 211 patients) who experienced vision loss (≥ 15 letters) unrelated to wet AMD; primary endpoint not achieved in full dataset, confounded by this asymmetric cohort –

– LUGANO demonstrated clinically meaningful results that reinforce DURAVYU's potential to improve the treatment paradigm in wet AMD, with compelling key secondary endpoints, including reduction in treatment burden, supplement-free rates, favorable safety profile with redosing, and strong anatomic control through Week 56 compared to on-label aflibercept –

– 42% reduction in treatment burden achieving superiority versus on-label aflibercept (nominal p-value of <0.0001) –

– 76% of DURAVYU patients were supplement-free up to Week 32 –

– 54% of DURAVYU patients were supplement-free and 79% received 0 or 1 supplement up to Week 56; pre-specified analysis on change in BCVA in the supplement-free DURAVYU patients showed non-inferiority to supplement-free aflibercept (nominal p-value = 0.0035) –

– Topline data from LUCIA, the second pivotal Phase 3 clinical trial in wet AMD, expected in Q4 2026 with potential FDA New Drug Application submission planned for 1H 2027 –

– Conference call to discuss the results to be held today at 8:00 a.m. EDT –

WATERTOWN, Mass., Aug. 17, 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 LUGANO, the first pivotal Phase 3 clinical trial for DURAVYU™ (vorolanib intravitreal insert) for the treatment of wet age-related macular degeneration (wet AMD).

DURAVYU was non-inferior to on-label aflibercept (nominal p-value = 0.0096) in an *ad hoc* analysis excluding a 4% asymmetric cohort (9 of 211 patients) who experienced vision loss (≥ 15 letters) unrelated to wet AMD. Despite the outperformance in key secondary endpoints, the primary endpoint of change from baseline in best corrected visual acuity (BCVA) versus 2 mg aflibercept on-label control was not achieved in the full dataset, confounded by this asymmetric cohort. In contrast, no patients experienced vision loss (≥ 15 letters) unrelated to wet AMD in the aflibercept control arm. In prior reported similar scale pivotal Phase 3 trials, approximately 3-5% of aflibercept patients lost ≥15 letters[1], indicating meaningful overperformance of the on-label aflibercept control group in LUGANO that also contributed to the primary endpoint performance.

LUGANO demonstrated clinically meaningful results that reinforce DURAVYU's potential to improve the treatment paradigm in wet AMD, with compelling key secondary endpoints in reduction in treatment burden, supplement-free rates, a favorable safety profile with redosing, and anatomic control through Week 56 compared to on-label aflibercept. These results represent a meaningful improvement to current wet AMD standard of care.

"We are pleased to see that DURAVYU provided clinically meaningful results in the LUGANO trial. The outstanding outcomes across key secondary endpoints, paired with visual improvement, reinforce our confidence in DURAVYU's potential to transform the current wet AMD treatment paradigm," said Jay S. Duker, M.D., President and CEO of EyePoint. "While the primary endpoint result for the full dataset was unexpected, the consistently positive results from the pre-specified secondary endpoints and the *ad hoc* analysis on the primary endpoint present a compelling case for DURAVYU as a new potential therapeutic option for wet AMD. We look forward to a potential New Drug Application (NDA) filing with FDA in the first half of 2027, pending LUCIA results in the fourth quarter of 2026."

Key Secondary Endpoints Across All Patients

Key secondary endpoints including a favorable safety profile, reduction in treatment burden, supplement-free rates, and anatomic controls were achieved.

- Favorable Safety Profile
  - DURAVYU observed to be safe and well tolerated with repeat dosing in patients
  - No difference in cataracts, elevated intraocular pressure, or intraocular inflammation between study and control group
  - No observed occurrences of insert migration, anterior chamber opacities, free-floating drug particles, retinal vasculitis, or severe intraocular inflammation (IOI)
- Reduction in Treatment Burden
  - 42% reduction in treatment burden, achieving superiority versus on-label aflibercept (nominal p-value<0.0001) compared to a maximum possible reduction of 60%
  - This reduction translates to two fewer injections on average in DURAVYU patients versus on-label aflibercept up to Week 56
- Supplement-Free Rates
  - 76% of DURAVYU patients were supplement-free up to Week 32
  - 94 % of DURAVYU patients received zero or one supplement up to Week 32
  - 54% of DURAVYU patients were supplement-free up to Week 56
  - 79% of DURAVYU patients received zero or one supplement up to Week 56
  - Pre-specified analysis of change in BCVA from baseline to average Week 52/56 in supplement-free patients showed that DURAVYU was non-inferior (nominal p-value=0.0035) versus on-label aflibercept
- Anatomic Control
  - Strong anatomic control demonstrated DURAVYU's potency with a mean difference of 4 microns versus on-label aflibercept control in central subfield thickness (CST) at Week 56
  - The 54% of DURAVYU eyes that were supplement free up to week 56 showed only a 3-micron difference in CST compared to the on-label aflibercept control

"The LUGANO results are clinically meaningful because the trial compared DURAVYU to on-label aflibercept, the current gold standard control group in wet AMD trials. Nearly 80% of DURAVYU-treated patients received one or no supplemental injections through Week 56. Disease control with this degree of durability, coupled with a favorable safety profile, would meaningfully reduce the treatment burden for our patients," said Carl D. Regillo, M.D., FACS, Former Director of the Wills Eye Hospital Retina Service, Professor of Ophthalmology, Thomas Jefferson University. "DURAVYU's ability to control disease well in the majority of patients with a six-month redosing interval represents a significant advance for our patients with wet AMD. In clinical practice, keeping patients adequately treated over time is a big challenge, and a sustained delivery option with this kind of profile would be a welcome addition to the armamentarium."

"DURAVYU demonstrated durable efficacy results with stable retinal anatomy maintained through Week 56, avoiding the sawtooth pattern commonly seen with intermittent anti-VEGF therapy. In addition, the supplement-free anatomic and visual outcomes further validate the potency of DURAVYU," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint. "These findings represent an important advancement for retinal disease treatment, demonstrating the potential for repeat dosing of a tyrosine kinase inhibitor (TKI), a capability unique to our clinical program, coupled with a favorable safety profile. We extend our sincere gratitude to the patients, caregivers, and investigators whose partnership and dedication made this study possible."

EyePoint plans to present additional details on the LUGANO dataset, including subgroup-analyses, at major retina conferences in the coming months, beginning at the Retina Society 59th Annual Scientific Meeting from September 23-26, 2026.

The Company remains on track to report topline data from the second wet AMD pivotal Phase 3 LUCIA trial in the fourth quarter of 2026. The Company anticipates potentially filing an NDA for DURAVYU for the potential treatment of wet AMD in the first half of 2027. Additionally, the pivotal Phase 3 COMO and CAPRI clinical trials for DURAVYU in diabetic macular edema (DME) rapidly completed enrollment, with topline data for both trials anticipated in the fourth quarter of 2027.

Conference Call Information

EyePoint management will host a conference call today, August 17, 2026, at 8:00 a.m. EDT to discuss the LUGANO topline results.

To access the live conference call and webcast, please register via the Events & Presentations page of the Investors section of 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 at the conclusion of the 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. 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 trials 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 results 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. LUCIA topline data results are expected in the fourth quarter of 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).

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 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, including the potential submission of a New Drug Application with FDA for DURAVYU ™ for the potential treatment of wet AMD in the first half of 2027; our confidence in DURAVYU as a potential treatment for wet AMD; our belief that vision loss experienced in the LUGANO Phase 3 clinical trial was not related to DURAVYU or lack of wet AMD control; 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 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 expectations regarding the timing of the availability and release of wet AMD and DME clinical data, including the reporting of LUCIA data in the fourth quarter of 2026 and topline results for Phase 3 COMO and CAPRI clinical trials in diabetic macular edema in the fourth quarter of 2027; our plans to present additional details on the LUGANO dataset, including subgroup-analyses, at major retina conferences in the coming months; 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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[1] Heier et al. Ophthalmology 2012 (VIEW 1/2), Bayer VIEW combined analysis; CADTH Beovu Clinical Review (NBK565336), HAWK/HARRIER wk48. ClinicalTrials.gov TENAYA Posted Results (NCT03823287). Accessed Aug. 15, 2026. ClinicalTrials.gov LUCERNE Posted Results (NCT03823300). Accessed Aug. 15, 2026. Center for Drug Evaluation and Research Statistical Review, BLA 761355Orig1s000.