EyePoint Completes Enrollment of Pivotal Phase 3 Trials for DURAVYU™ in Wet Age-Related Macular Degeneration

Jul 29, 2025

– LUCIA pivotal Phase 3 trial enrolled and randomized over 400 patients in seven months, demonstrating continued strong enthusiasm for the DURAVYU pivotal program across the global retinal community –

– Over 800 patients enrolled across the LUGANO and LUCIA trials of DURAVYU, representing one of the fastest enrolling Phase 3 pivotal programs for wet AMD –

– Interim analysis by independent Data Safety Monitoring Committee (DSMC) confirmed no changes to Phase 3 protocol and recommended continuation of trial as planned –

– Topline 56-week data for LUGANO expected in mid-2026 with LUCIA to closely follow –

WATERTOWN, Mass., July 29, 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 it has completed enrollment of its Phase 3 pivotal program with the full enrollment of the LUCIA trial, the second of two identical ongoing pivotal non-inferiority trials evaluating DURAVYU ™ for the treatment of wet age-related macular degeneration (wet AMD). The first pivotal trial, LUGANO, completed enrollment in May 2025. The LUCIA trial has enrolled and randomized over 400 patients in seven months making DURAVYU one of the fastest enrolling Phase 3 pivotal programs in wet AMD.

The Company also announced that based on interim masked safety data, the safety profile observed in LUGANO and LUCIA is consistent with previous DURAVYU clinical trials. DURAVYU has been evaluated in over 190 patients across four clinical trials demonstrating a favorable safety and tolerability profile including no DURAVYU related ocular or systemic serious adverse events observed. In parallel, an independent Data Safety Monitoring Committee (“DSMC”) convened and recommended continuation of the program as planned.

LUGANO and LUCIA are supported by the robust safety and efficacy data from the DAVIO 2 Phase 2 clinical trial. The Phase 3 pivotal program was developed in alignment with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), follows recognized industry best practices, and is strategically designed to enhance the potential for regulatory and commercial success. All patients are randomized on Day One and immediately begin treatment with a one-year efficacy and safety endpoint to support an NDA filing. With the completion of enrollment for LUCIA, topline data is anticipated to follow shortly after topline data for LUGANO which is expected in mid-2026.

“With enrollment now complete for our Phase 3 wet AMD program, well ahead of our expectations, we continue to demonstrate exceptional execution and our deep commitment to the retinal disease community,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. “The industry-leading pace of our clinical program is a testament to the patient and physician enthusiasm for innovative, novel and more durable wet AMD treatments and DURAVYU’s compelling and differentiated profile. As we look ahead to anticipated topline data for LUGANO in mid-2026 and LUCIA to follow, we remain focused on bringing the first sustained-release TKI for wet AMD to market and advancing our mission of delivering transformative treatment options for patients.”

“Similar to our LUGANO trial, LUCIA has exceeded enrollment timelines, underscoring our clinical development leadership and continued recognition by the retinal community of DURAVYU’s best-in-class profile,” said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer at EyePoint. “We are proud of the clinical rigor and patient-centric approach underpinning our Phase 3 program, including our real-world design, which has now been approved by both the U.S. and European regulatory bodies, as well as use of an on-label standard of care comparator that resonates with physicians. LUCIA also marked our expansion beyond the U.S. with patient participation in South America, Europe, Israel, Australia and India, demonstrating global momentum and interest in DURAVYU. We are excited to be one step closer towards bringing our innovative sustained-release TKI to wet AMD patients seeking more durable therapies that reduce the treatment burden.”

“The rapid enrollment of the LUCIA trial reflects its patient-centric design, DURAVYU’s excellent safety profile, and EyePoint’s ongoing engagement with the retinal community,” said Anat Loewenstein, M.D., MHA, Vice President Ambulatory Services, Head of Retina Tel Aviv Medical Center, President of European Society of Retina Specialists (EURetina) and member of EyePoint’s Scientific Advisory Board. “With its use of a non-inferiority design and on-label aflibercept control, EyePoint’s Phase 3 program is

designed to generate data that is relevant to clinical practitioners like myself. Additionally, the 6-month redosing schedule being evaluated would enable greater clinical flexibility and improved compliance for patients, representing a potential paradigm shift for the treatment of wet AMD. It is my pleasure to contribute to this cutting-edge research, which holds the promise of improving outcomes for retinal disease patients worldwide."

LUGANO and LUCIA are randomized, double-masked, aflibercept controlled, non-inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU in patients with active wet AMD including treatment naïve and treatment experienced patients. Enrollment is complete in both trials with over 400 patients enrolled in each trial. Patients are randomized 1:1 to receive either DURAVYU 2.7mg or an on-label aflibercept control. 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. Patients in the DURAVYU 2.7mg treatment arm will receive an intravitreal dose of DURAVYU every six months, starting at month two of the trial. DURAVYU is delivered via a standard intravitreal injection in the physician's office, similar to current standard practice with FDA approved anti-VEGF treatments. The primary endpoint of the Phase 3 pivotal trials is the average change in best corrected visual acuity (BCVA) at weeks 52 and 56 versus 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 trial 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 condition that develops when abnormal blood vessels grow into the macular retina, leaking blood 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, f/k/a EYP-1901), is being developed as a potential sustained-delivery treatment for patients suffering from VEGF-mediated retinal diseases. It is designed to be administered intravitreally in a pre-loaded syringe injector and deliver a daily therapeutic dose for at least six months. DURAVYU combines vorolanib in the Durasert E ™ technology: Durasert E is EyePoint's proprietary and best-in-class bioerodible sustained release insert with a matrix designed to prevent free-floating drug particles and contains no PEG or PLGA; vorolanib is a differentiated and patent-protected tyrosine kinase inhibitor (TKI) and is the most studied TKI in retinal disease, with proven ocular safety and no TIE2 inhibition. Vorolanib brings a novel mechanism of action to the treatment of VEGF-mediated retinal diseases as it works intracellularly to inhibit all VEGF receptors. Benefits of this new mechanistic approach include the demonstration of neuroprotection in an in vivo model of retinal detachment, as well as blockage of PDGF, which may have potential antifibrotic benefits.

DURAVYU has efficacy data across approximately 140 wet acute 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.

An ongoing Phase 3 pivotal program, consisting of two trials, LUGANO and LUCIA, is evaluating re-dosing of DURAVYU in wet AMD. 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). The Phase 2 VERONA trial 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. These positive Phase 2 results support the advancement of the DME program to a Phase 3 pivotal program and the Company recently completed a positive End-of-Phase 2 meeting with the FDA.

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 VEGF-mediated 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 to date, DURAVYU is currently being evaluated in two Phase 3 pivotal trials for wet age-related macular degeneration (wet AMD) with topline data anticipated in 2026. DURAVYU also completed a positive Phase 2 clinical trial in diabetic macular edema (DME) with Phase 3 pivotal planning underway. Despite current therapies, patients with wet AMD and DME still tend to lose vision in the long term and wet AMD is the leading cause of vision loss among

people 50 years of age and older in the United States.

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 belief that DURAVYU is on track to be the first-to-market of the current investigational sustained release treatments for wet AMD; our belief that DURAVYU has two potential blockbuster indications; our belief that DURAVYU's potential real-world application in multiple retinal disease indications and de-risked trial designs position DURAVYU for clinical and commercial success; our expectations regarding timing for the completion of clinical trial enrollment and the timing of the availability and release of clinical data; our belief that rapid trial enrollment in LUGANO and LUCIA highlights physician and patient enthusiasm for DURAVYU, which we believe is driven by an established and familiar trial design, robust Phase 2 data, and a strong safety profile; our expectations regarding cash runway; our optimism that that DURAVYU has the potential to shift the treatment paradigm in wet AMD and DME and improve patient outcomes; our expectations regarding clinical development of our other product candidates, including EYP-2301; our belief that we are well positioned as the leader in ocular sustained drug delivery; 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; 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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