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

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– Over 400 patients enrolled and randomized over a seven-month period, driven by strong physician and patient interest –

– LUCIA pivotal Phase 3 trial continues rapid enrollment pace with 60% of patients randomized; enrollment completion expected in 3Q 2025 –

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

WATERTOWN, Mass., May 27, 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 enrolled and randomized over 400 patients in the Phase 3 LUGANO pivotal trial of DURAVYU™ for the treatment of wet age-related macular degeneration (wet AMD) exceeding its enrollment target. The seven-month enrollment for LUGANO represents one of the fastest enrolling Phase 3 pivotal trials for wet AMD to date.

LUGANO is the first of two pivotal non-inferiority trials underway in the Phase 3 program of DURAVYU for the treatment of wet AMD. Supported by the robust DAVIO 2 Phase 2 clinical trial in over 160 patients, the Phase 3 pivotal program was developed in direct alignment with the U.S. Food and Drug Administration (FDA), follows recognized industry best practices, and is strategically designed to enhance the potential for regulatory and commercial success. All patients are randomized on Day 1 and immediately begin treatment with a one-year efficacy and safety endpoint. With the completion of enrollment for LUGANO, topline data is anticipated in mid-2026.

“The rapid enrollment of the Phase 3 LUGANO trial is a testament to the significant patient and physician enthusiasm for our Phase 3 program and underscores the tremendous patient need and commercial market potential for DURAVYU,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. “We are committed to bringing the first sustained-release tyrosine kinase inhibitor (TKI) to market for patients and physicians in need of a new treatment option for wet AMD. With both pivotal trials continuing to exceed our timelines, we now expect topline data for the LUGANO trial in mid-2026 with LUCIA to follow in the second half of 2026.”

“The excitement for DURAVYU within the retinal community highlights its potential to transform the treatment paradigm for wet AMD patients. It also reflects the strong appeal of our trial design, which is supported by a well-established safety profile in over 190 patients,” said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint. “With enrollment in the LUGANO trial completed, our focus is on completing enrollment for the LUCIA trial in the third quarter of 2025. We expect continued strong momentum, as sites outside the US are now actively enrolling and select LUGANO sites are preparing to cross over to LUCIA.”

“The pace of enrollment in the LUGANO trial highlights EyePoint’s engagement with the retinal community and underscores the enthusiasm for this patient-centric pivotal program for DURAVYU,” said Brittney Statler, M.D., Principal Investigator in the LUGANO clinical trial and Medical Retina Specialist at Panorama Eyecare. “One of the many compelling elements of this program is the fact that all patients receive active treatment with either aflibercept or DURAVYU, enabling us to effectively evaluate this potential next generation treatment for wet AMD in a real-world clinical practice setting. We are honored to be part of this innovative clinical research for a treatment that has the potential to change the current treatment paradigm and revolutionize clinical outcomes for patients suffering from serious retinal diseases.”

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. The LUGANO trial has enrolled and randomized over 400 patients, and the LUCIA trial is also designed to enroll approximately 400 patients globally who will be randomly assigned to 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™, f/k/a EYP-1901, is being developed as a potential sustained-delivery maintenance treatment for patients suffering from chronic VEGF-mediated retinal diseases. DURAVYU delivers vorolanib, a differentiated and patent-protected tyrosine kinase inhibitor (TKI), as a solid bioerodible insert using EyePoint's proprietary and best-in-class bioerodible Durasert E™ technology. Vorolanib brings a new mechanism of action to the treatment of VEGF-mediated retinal diseases as a potent and highly selective pan-VEGF receptor inhibitor. 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 established a robust safety and efficacy profile with the largest TKI intravitreal (IVT) trial dataset in wet AMD to-date. Positive data from Phase 1 and Phase 2 (DAVIO 2) clinical trials of DURAVYU in wet AMD demonstrated clinically meaningful efficacy data with stable visual acuity and CST and a favorable safety profile. Data from DAVIO 2 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. DURAVYU is being studied in two ongoing Phase 3 clinical trials, LUGANO and LUCIA, in wet AMD. The Phase 3 pivotal programs are evaluating re-dosing of DURAVYU with the goal of providing the retina community valuable insight into sustained 'real-world' usage of DURAVYU.

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 an immediate 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 which will be informed by an EOP2 meeting with FDA.

About EyePoint

EyePoint Pharmaceuticals, Inc. (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU™ is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with bioerodible Durasert E ™. Supported by robust safety and efficacy data to date, DURAVYU is presently in Phase 3 global, pivotal clinical trials for wet age-related macular degeneration, the leading cause of vision loss among people 50 years of age and older in the United States and recently completed a Phase 2 clinical trial in diabetic macular edema.

The proven Durasert® drug delivery technology has been safely administered to thousands of patient eyes across four U.S. FDA approved products in multiple disease indications. EyePoint is headquartered in Watertown, Massachusetts, and operates a commercial-scale 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 candidate; 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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