EyePoint Pharmaceuticals Announces First Patient Dosed in Global Phase 3 LUGANO Clinical Trial of DURAVYU™ for the Treatment of Wet Age-Related Macular Degeneration

October 24, 2024

– Second Phase 3 LUCIA pivotal trial first patient dosing expected by end of 2024 –

– Topline data anticipated in 2026 –

WATERTOWN, Mass., Oct. 24, 2024 (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 that the first patient has been dosed in the Phase 3 LUGANO clinical trial of DURAVYU™, formerly EYP-1901, for the treatment of wet age-related macular degeneration (wet AMD). DURAVYU is an investigational sustained delivery therapy delivering patent-protected vorolanib, a selective tyrosine kinase inhibitor formulated in proprietary bioerodible Durasert E™.

“Dosing the first patient in the global Phase 3 LUGANO trial represents a significant milestone for EyePoint and DURAVYU, underscoring our leadership in sustained-release ocular drug delivery and commitment to developing innovative therapies for patients with serious retinal diseases,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. “Our Phase 3 LUGANO and LUCIA trials were designed for potential global regulatory and commercial success based on our alignment with the FDA, as they follow a proven non-inferiority approval pathway. We have entered Phase 3 leveraging learnings from our robust DAVIO and DAVIO 2 clinical trials to facilitate accelerated enrollment so that wet AMD patients may receive this potentially paradigm-shifting treatment as fast as possible.”

“With over 150 clinical trial sites already committed, we believe we are well positioned to rapidly enroll patients globally in the pivotal LUGANO trial, with the LUCIA trial to quickly follow,” said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint. “We are encouraged by the exceptional patient and investigator enthusiasm for our Phase 3 protocol, which aligns with clinical practice by including active treatment through trial duration. Patients will receive DURAVYU every six months or on-label aflibercept every two months, beginning after three loading doses of aflibercept with randomization occurring on Day 1. Further, the trials include both treatment-naïve and treatment experienced patients, which we believe more accurately represent the real-world patient population and increases our probability of success based on the positive DAVIO 2 data. We are optimistic that DURAVYU has the potential to change the current treatment paradigm and revolutionize clinical outcomes for patients suffering from serious retinal diseases.”

“Wet AMD patients face significant unmet need for a safe and efficacious sustained delivery treatment, as the current standard of care requires frequent injections resulting in a high treatment burden and, ultimately, delayed or missed appointments that potentially leave patients with no active drug to prevent disease progression and associated vision loss,” said Dr. Carl Regillo, M.D., FACS, Director of Retina Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University. “Based on the promising clinical data generated in the DAVIO and DAVIO 2 trials, as well as the favorable safety profile from over 190 patients treated, I believe DURAVYU has the potential to improve the treatment paradigm for this lifelong disease by maintaining a majority of patients with active disease with no supplemental anti-VEGF therapy for six months or longer. The pivotal trials of DURAVYU in wet AMD represent an exciting milestone for patients, caregivers and physicians as we work to improve quality of life and patient vision.”

“Despite new treatments entering the wet AMD market, there remains a need for safe and durable treatments that provide sustained treatment while decreasing the patient’s need for frequent injections,” said Ashkan M. Abbey, M.D., a principal investigator in the LUGANO clinical trial and Director of Clinical Research at Texas Retina Associates. “DURAVYU brings a new mechanism of action with the potential to treat wet AMD patients every six months or longer to actively safeguard patients’ vision between visits. We are proud to be the first site to treat a patient in the LUGANO clinical trial, and we look forward to continuing to collaborate with EyePoint to rapidly enroll patients.”

LUGANO and LUCIA are global, randomized, double-masked, aflibercept controlled, non-inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU in patients with active wet AMD including previously treated and treatment-naïve patients. Each trial is expected to enroll approximately 400 patients globally who will be randomly assigned to a 2.7mg dose of DURAVYU or an on-label aflibercept control. The LUGANO and LUCIA trials are the only sustained release wet AMD pivotal Phase 3 trials evaluating re-dosing in both trials. Patients in the DURAVYU treatment arm will receive an intravitreal injection 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).

About Wet AMD

Age-related macular degeneration (AMD) is a leading cause of vision loss and irreversible blindness in people over the age of 50. 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 paradigm-altering treatment for patients suffering from VEGF-mediated retinal

diseases. DURAVYU delivers vorolanib, a potent, selective and patent-protected tyrosine kinase inhibitor (TKI) as a solid bioerodible insert using EyePoint's proprietary sustained-release Durasert E ™ technology. Vorolanib brings a new mechanistic approach to the treatment of VEGF-mediated retinal diseases as a pan-VEGF receptor inhibitor, inhibiting all VEGF receptors. Further, in an in-vivo model of retinal detachment, vorolanib demonstrated neuroprotection and may have antifibrotic benefits as it also blocks PDGF. DURAVYU is shipped and stored at ambient temperature and is administered with a standard intravitreal injection in the physician's office. DURAVYU is immediately bioavailable with zero-order kinetics release for up to nine months.

Positive data from both the Phase 1 DAVIO 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. Further, data from DAVIO 2 demonstrated an impressive treatment burden reduction of approximately 88% at eight months, six months after treatment with DURAVYU, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection through up to eight months, six months after treatment with DURAVYU. The data from the DAVIO 2 clinical trial supported the advancement of the wet AMD program and the initiation of the Phase 3 LUGANO trial, with the LUCIA pivotal trial to follow by year end 2024.

DURAVYU is also currently being studied in the Phase 2 VERONA trial for diabetic macular edema (DME). Topline data is expected in the first quarter of 2025.

About EyePoint Pharmaceuticals

EyePoint (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 ™ (f/k/a EYP-1901), 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 ™. DURAVYU is presently in Phase 3 global, pivotal clinical trials as a sustained delivery treatment for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States, and in a Phase 2 clinical trial in diabetic macular edema (DME). EyePoint expects topline data from the Phase 2 clinical trial in DME in Q1 2025 and topline data from both Phase 3 pivotal trials in wet AMD in 2026.

Pipeline programs include EYP-2301, a TIE-2 agonist, razuprotafib, formulated in Durasert E ™ to potentially improve outcomes in serious retinal diseases. The proven Durasert® drug delivery technology has been safely administered to thousands of patient eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, 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 PHARMACEUTICALS 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 the timing and clinical development of DURAVYU in wet AMD and DME, including our expectations regarding the enrollment, dosing and data readouts for the LUGANO trial and the LUCIA trial; our optimism that that DURAVYU has the potential to change the current treatment paradigm and revolutionize real-world outcomes for patients suffering from serious retinal diseases; our belief that DURAVYU has the potential to maintain a majority of patients with active disease with no supplemental anti-VEGF therapy for six months or longer; our expectations regarding the timing and clinical development of our other product candidates, including EYP-2301; and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," 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 the design, enrollment, completion, and results of clinical trials; 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 data are subject to further analysis; 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; 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. 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.

Investors:
Christina Tartaglia
Precision AQ
Direct: 212-698-8700

christina.tartaglia@precisionaq.com

Media Contact:
Amy Phillips
Green Room Communications
Direct: 412-327-9499
aphillips@greenroompr.com

Source: EyePoint Pharmaceuticals, Inc.