EyePoint Provides Company Update and Anticipated Development Milestones for 2025

January 13, 2025

– Enrollment in DURAVYU Phase 3 wet AMD clinical trials exceeding expectations with the LUGANO trial one-third enrolled and the LUCIA trial tracking ahead of schedule –

– Full data for Phase 2 VERONA clinical trial of DURAVYU in DME expected in 1Q 2025 –

– Appointed renowned retina specialist and industry leader Reginald J. Sanders, M.D., FASRS to Board of Directors –

– Cash runway into 2027 beyond topline DURAVYU Phase 3 wet AMD data expected in 2026 –

– Presenting at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco on Tuesday, January 14, 2025 at 2:15 p.m. PT –

WATERTOWN, Mass., Jan. 13, 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 provided a company update and anticipated 2025 milestones for its lead product candidate, DURAVYU™ (vorolanib intravitreal insert), f/k/a EYP-1901. DURAVYU is an investigational sustained delivery therapy delivering patent-protected vorolanib, a selective tyrosine kinase inhibitor (TKI) formulated in proprietary bioerodible Durasert E™ for sustained intraocular delivery.

“2024 was an exceptional year for EyePoint, positioning us for continued success and execution in 2025,” said Jay Duker, M.D., President and Chief Executive Officer. “Most importantly, as we step into 2025, both of our global Phase 3 clinical trials for DURAVYU in wet AMD are now fully underway with enrollment in both trials exceeding our expectations. The LUGANO trial has already enrolled approximately one-third of planned patients, and the LUCIA trial is tracking ahead of schedule after an accelerated initiation in December. We expect to fully enroll these trials in the second half of 2025. We remain very excited by the large market opportunity for DURAVYU in diabetic macular edema (DME) where 16-week interim data demonstrated early and sustained improvement in BCVA and CST. We look forward to final VERONA data as well as alignment with the FDA and EMA in the coming months to finalize our Phase 3 plan for this important indication.”

Dr. Duker continued, “We continue our track record of strong execution with the opening of our new, state-of-the-art Northbridge, MA manufacturing facility in the fall of 2024. The 40,000 plus square-foot manufacturing facility reflects our commitment to quality and commercial readiness for DURAVYU. With two simultaneous Phase 3 clinical trials underway, the most robust clinical dataset of all long-acting treatments in development for wet AMD, an impressive patent portfolio for DURAVYU, and a strong balance sheet, we are well-positioned to advance our mission of bringing potentially life-changing therapeutics to patients suffering from serious retinal diseases globally.”

The Leader in Sustained Ocular Drug Delivery:

- Global Phase 3 LUGANO and LUCIA pivotal trials of DURAVYU in wet AMD underway. Enrollment completion of both trials is expected in 2H 2025, with topline data anticipated in 2026.
- DURAVYU Phase 3 pivotal design is the only sustained delivery wet AMD program evaluating six-month re-dosing in both trials.
- The LUGANO and LUCIA trials are also designed to provide data on the efficacy, durability, and safety of DURAVYU and provide the retina community with valuable insight on how DURAVYU could be used in ‘real-world’ practice.
- DURAVYU was evaluated in the largest Phase 2 clinical trial to date (DAVIO 2) of all sustained delivery programs in development, meeting all primary and secondary endpoints.
- DURAVYU is the only sustained release TKI being evaluated in DME.
    - Positive interim 16-week data from the Phase 2 VERONA clinical trial demonstrated DURAVYU 2.7mg meaningfully improved patients with active DME better than aflibercept alone both anatomically and visually with CST (central subfield thickness) improvement of 68.1 microns and a BCVA gain of +8.9 letters vs. baseline. Notably, both DURAVYU doses showed an immediate benefit demonstrating the unique drug release profile of DURAVYU.
    - Full topline data from the Phase 2 VERONA clinical trial is expected in 1Q 2025 with interactions with the FDA and the European Medicines Agency (EMA) on Phase 3 plans to follow.
- DURAVYU has the most robust safety database among sustained delivery treatments with over 190 patients dosed across multiple indications, with no DURAVYU related ocular or systemic serious adverse events reported.
- EyePoint’s Durasert technology has been utilized in four FDA approved products with an established favorable safety profile in thousands of patients.

Corporate Updates

- In January 2025, EyePoint appointed renowned retina specialist and industry pioneer Reginald J. Sanders, M.D., FASRS to the Board of Directors.
- In October 2024, EyePoint announced the opening of its Northbridge, MA cGMP commercial manufacturing facility built to meet U.S. FDA and EMA standards. It will support global manufacturing across the Company’s portfolio, including lead

pipeline asset, DURAVYU™ upon potential regulatory approval. The facility is strategically designed to support the Company's next phase of growth and broadens EyePoint's manufacturing capabilities with capacity for pipeline expansion.

- Approximately $370 million[1] of cash and investments at December 31, 2024 with cash runway into 2027 beyond topline Phase 3 data for DURAVYU in wet AMD expected in 2026.
- EyePoint will present at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco on Tuesday, January 14, 2025 at 2:15 p.m. PT/5:15 p.m. ET. Jay S. Duker, M.D., President and Chief Executive Officer, will provide a company update on clinical and regulatory progress and highlight upcoming milestones. A webcast and subsequent archived replay of the presentation may be accessed via the Investors section of the Company website at www.eyepointpharma.com.

[1]Unaudited estimate as of December 31, 2024.

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. 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 at least six months.

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. The DAVIO 2 clinical trial data supported the initiation of the current global Phase 3 clinical trials, LUGANO and LUCIA in wet AMD.

DURAVYU is also currently being studied in the Phase 2 VERONA trial for diabetic macular edema (DME) with positive interim 16-week results for both safety and efficacy. Full 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™ 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 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). Full 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 and potential of DURAVYU in wet AMD and DME, including our expectations regarding the announcement of full topline data from the VERONA trial in the first quarter of 2025 and the progress of our ongoing LUGANO and LUCIA trials; the belief that the interim results from the VERONA trial support DURAVYU's potential to advance to non-inferiority pivotal trials; our beliefs and expectations regarding the anticipated full results from the VERONA trial; the potential for DURAVYU 2.7mg to extend treatment intervals while improving vision; the potential for DURAVYU to provide an immediate benefit over aflibercept control in both BCVA and CST; our optimism that that DURAVYU has the potential to shift the treatment paradigm in DME and improve patient outcomes; our expectations regarding clinical development of our other product candidates, including EYP-2301; our business strategies and objectives; 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 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; 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.

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