EyePoint Pharmaceuticals Completes Enrollment in Oversubscribed Phase 2 DAVIO 2 Clinical Trial of EYP-1901 for Maintenance Treatment of Wet AMD

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- Significant investigator and patient interest drove strong recruitment, exceeding enrollment goals

- Topline DAVIO 2 data anticipated in Q4 2023

WATERTOWN, Mass., March 27, 2023 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced it has completed enrollment in the Phase 2 "Durasert® and Vorolanib in Ophthalmology 2" (DAVIO 2) clinical trial evaluating EYP-1901 as a potential six-month maintenance treatment for wet age-related macular degeneration (wet AMD). The trial exceeded its original target of 144 patients, enrolling a total of 160 patients. All patients were previously treated with a standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of EYP-1901 or to an aflibercept on-label control.

“We are thrilled to announce the completion of enrollment in our oversubscribed Phase 2 DAVIO 2 trial evaluating EYP-1901 in wet AMD, marking an important milestone as we continue to advance our pipeline of innovative sustained delivery treatments for serious eye disorders,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. “Patients with wet AMD face an immense treatment burden, requiring monthly or bi-monthly eye injections for the rest of their lives in order to prevent severe vision loss. The high level of patient and physician interest we saw in the trial enrollment further demonstrates the great unmet need in this population for a maintenance treatment option that is safe, effective, long-lasting and convenient.”

“We look forward to reporting topline data in the fourth quarter of this year. With these data and the promising results from our Phase 1 DAVIO trial, EYP-1901 will have the largest and most robust dataset of any tyrosine kinase inhibitor (TKI) product in development for wet AMD. These data will inform the design of our pivotal Phase 3 clinical trials and provide optionality as we seek to bring this promising product to patients. I would like to thank our dedicated team of employees and clinical partners, as well as the patients who enrolled in the Phase 1 and Phase 2 EYP-1901 trials and their caregivers for advancing the development of EYP-1901,” continued Ms. Lurker.

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with wet AMD. Originally designed to enroll 144 patients, the trial enrolled 160 patients in total due to strong investigator and patient interest. All enrolled patients were previously treated with a standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg) or an aflibercept control. EYP-1901 is delivered with a single intravitreal injection in the physician's office, similar to current FDA approved anti-VEGF treatments. The primary efficacy endpoint of the DAVIO 2 trial is change in best corrected visual acuity (BCVA) compared to the aflibercept control, six-months after the EYP-1901 injection. Secondary efficacy endpoints include change in central subfield thickness (CST) as measured by optical coherence tomography (OCT), number of eyes that remain free of supplemental anti-VEGF injections, number of aflibercept injections in each group, and safety. More information about the trial is available at clinicaltrials.gov (identifier: NCT05381948).

“Our ‘Treat to Maintain’ therapeutic approach for EYP-1901 has the potential to transform the wet AMD treatment paradigm, and we are incredibly pleased to complete enrollment with more patients than planned in the DAVIO 2 clinical trial due to high demand to participate from investigators and patients,” said Jay Duker, M.D., President and Chief Operating Officer of EyePoint Pharmaceuticals. “The compelling Phase 1 DAVIO results demonstrate EYP-1901’s potential to transition a majority of patients to an every-six-month treatment for wet AMD, representing a ‘treat to maintain’ therapeutic approach that uses EYP-1901 as a baseline therapy following the use of large molecule anti-VEGFs with the goal of significantly extending the patient’s treatment interval. Based on the extensive prior clinical data evaluating Durasert in four FDA-approved indications, we are confident in EYP-1901’s ability to consistently deliver the active drug, vorolanib, with zero-order drug release kinetics using our bioerodible sustained delivery technology, Durasert® E. In addition, vorolanib brings a new mechanism of action for wet AMD patients and may have additional neuroprotective benefits. We are confident in EYP-1901’s potential to enhance treatment compliance, improve clinical experience and, ultimately, result in better patient outcomes.”

Topline data from the Phase 2 DAVIO 2 trial of EYP-1901 in wet AMD is anticipated in Q4 2023.

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment combining a bioerodible formulation of EyePoint's proprietary Durasert® delivery technology (Durasert® E) with vorolanib, a tyrosine kinase inhibitor. Positive safety and efficacy data from the DAVIO Phase 1 clinical trial of EYP-1901 showed a positive safety profile with stable visual acuity and OCT. Further, 53% and 35% of eyes did not require any supplemental anti-VEGF injections up to six and twelve months, respectively, following a single dose of EYP-1901. Phase 2 studies are underway for wet AMD and non-proliferative diabetic retinopathy and are planned in diabetic macular edema. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary Durasert® technology for sustained intraocular drug delivery including EYP-1901, an investigational sustained delivery intravitreal anti-VEGF treatment currently in Phase 2 clinical trials. The proven Durasert drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products, including YUTIQ® for the treatment of posterior segment uveitis, which is currently marketed by the Company. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

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 the use of proceeds for the offering 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, this includes uncertainties regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration and non-proliferative diabetic retinopathy; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the success of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of competition and other developments affecting sales of our commercialized products, YUTIQ® and DEXYCU®; the loss of pass-through reimbursement status for DEXYCU as of January 1, 2023; market acceptance of our products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; the potential impact of the COVID-19 pandemic on EyePoint's business, the medical community and the global economy; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; 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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