



EyePoint Pharmaceuticals Completes Enrollment in Phase 2 PAVIA Clinical Trial of EYP-1901 in Non-Proliferative Diabetic Retinopathy

June 5, 2023

– Significant investigator and patient interest drove strong recruitment of 77 patients exceeding the 60 patient target –

– Topline PAVIA data anticipated in 2Q 2024 –

WATERTOWN, Mass., June 05, 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 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment for moderate to severe non-proliferative diabetic retinopathy (NPDR).

"We are delighted to report the completion of enrollment in the Phase 2 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment for NPDR," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "We are particularly pleased to have enrolled 77 patients in this trial, exceeding the 60 patient target, and look forward to reporting topline data in the second quarter of 2024. We are excited about the potential of EYP-1901 in NPDR. Despite the risk for visual loss associated with this disease, over 90% of patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is due to the burdensome and frequent eye injections currently required with today's approved therapies for this disease. As a result, we believe EYP-1901 may address the substantial therapeutic unmet need for a long-acting treatment."

PAVIA is a 12-month, randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with moderate to severe NPDR. The trial enrolled 77 patients randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg), or to the control group receiving a sham injection. EYP-1901 is delivered with a single intravitreal injection in the physician's office. The primary efficacy endpoint of the trial is improvement of at least two diabetic retinopathy severity scale (DRSS) levels as of week 36 after the EYP-1901 injection. Secondary endpoints include reduction in vision-threatening complications, occurrence of diabetic macular edema and/or proliferative disease, retinal ischemia/nonperfusion and safety. More information about the study is available at clinicaltrials.gov (identifier: NCT05383209).

"NPDR is a serious eye disorder affecting almost one-third of adults over the age of 40 with diabetes. It can lead to severe vision loss if left uncontrolled, however, the only approved treatments for this chronic disease are short-acting and require frequent office visits and intraocular injections. This leads to a passive treatment approach with no active drug therapy as the existing standard-of-care," said Jay S. Duker, M.D., President and Chief Operating Officer of EyePoint Pharmaceuticals. "There was a high-level of enthusiasm from practitioners, caregivers, and patients during the enrollment of the PAVIA trial, and, speaking from my experience as a practicing retina specialist, I am incredibly excited about the potential of treating NPDR patients with EYP-1901 every 9-months or longer to actively safeguard patients' vision between eye examinations. We thank the trial investigators, patients, and our internal team for completing trial enrollment swiftly and for their continued confidence in EYP-1901."

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment for retinal disease combining an erodible formulation of EyePoint's proprietary Durasert[®] delivery technology (Durasert E[™]) with vorolanib, a tyrosine kinase inhibitor. Positive safety and efficacy data from the Phase 1 DAVIO clinical trial of EYP-1901 in wet AMD showed a positive safety profile with stable visual acuity and OCT. Further, the data demonstrated an impressive treatment burden reduction of 75% at six months and 73% at the 12-month visit following a single dose of EYP-1901. Phase 2 trials are fully enrolled in wet AMD and non-proliferative diabetic retinopathy, and a diabetic macular edema trial is planned for initiation in Q1 2024. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

About Non-Proliferative Diabetic Retinopathy

Diabetic retinopathy affects approximately 40 percent of people with diabetes and is projected to impact 14.6 million Americans by 2050. Non-proliferative diabetic retinopathy (NPDR) is the early stage of the disease in which symptoms may be mild or nonexistent. In NPDR, the blood vessels in the retina are weakened, and tiny bulges in the blood vessels, called microaneurysms, may leak fluid into the retina. This leakage may lead to swelling of the macula and cause vision changes and blurriness. NPDR can lead to more serious complications or severe vision loss if left uncontrolled. The current standard-of-care for patients with moderate to severe NPDR includes intravitreal injections of anti-VEGF agents or laser photocoagulation, which can become a burden on patients, caregivers, and physicians due to the longevity of the disease and need for consistent therapies.

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 erodible Durasert E[™] 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. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. For more information visit www.eyepointpharma.com.

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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 our ability to realize the anticipated benefits of the 2023 sale of YUTIQ® to Alimera Sciences including our potential to receive additional payments from Alimera pursuant to the our agreements with Alimera; our ability to manufacture YUTIQ in sufficient quantities pursuant to our commercial supply agreements with Alimera and Ocumension Therapeutics; 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, non-proliferative diabetic retinopathy and diabetic macular edema; 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, including our agreements with Alimera, Ocumension, Equinox Science and Betta Pharmaceuticals; termination or breach 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; market acceptance of our products, including our out-licensed products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; the extent to which COVID-19 impacts our business and the medical community; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; the sufficiency of the Company's cash resources and need for additional financing; 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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Source: EyePoint Pharmaceuticals, Inc.