EyePoint Pharmaceuticals Announces First Patient Dosed in Phase 2 PAVIA Clinical Trial of EYP-1901 for the Treatment of Non-Proliferative Diabetic Retinopathy

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WATERTOWN, Mass., Sept. 29, 2022 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced that the first patient has been dosed in the Phase 2 PAVIA clinical trial of EYP-1901, a potential sustained delivery intravitreal anti-vascular endothelial growth factor (anti-VEGF) treatment targeting non-proliferative diabetic retinopathy (NPDR).

“We are excited to announce the first patient dosing of the Phase 2 PAVIA clinical trial of EYP-1901 for NPDR, a serious eye disorder affecting almost one-third of adults over the age of 40 with diabetes that can lead to severe vision loss if left uncontrolled,” said Jay Duker, M.D., Chief Operating Officer of EyePoint Pharmaceuticals. “Despite the severe nature of this disease, the current standard-of-care is no treatment until a patient develops sight-threatening complications. There remains a lack of approved treatments for this serious eye disease, leaving a significant opportunity for a long-acting treatment option that maintains the patient’s existing vision proactively. Building on EYP-1901’s excellent safety and efficacy results from our Phase 1 DAVIO trial in wet AMD, we believe that EYP-1901 has the potential to improve the current treatment paradigm as a sustained delivery maintenance treatment for NPDR and significantly improve the lives of patients living with this serious eye disorder.”

The 12-month, randomized, controlled Phase 2 PAVIA clinical trial of EYP-1901 for NPDR is expected to enroll approximately 105 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) severity levels as of week 36 after the EYP-1901 injection. Secondary endpoints include vision-threatening complications, occurrence of DME and/or proliferative disease, retinal ischemia/nonperfusion and safety. More information about the study is available at clinicaltrials.gov (identifier: NCT05383209).

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 with vorolanib, a tyrosine kinase inhibitor. Positive safety and efficacy data from the DAVIO Phase 1 clinical trial of EYP-1901 showed no reports of ocular or drug-related systemic serious adverse events and no dose limiting toxicities 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 for diabetic macular edema in 2023. 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 about 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 mild 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 experiencing vision loss include 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 pharmaceutical 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.

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 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; 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®; 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 continued impact of the COVID-19 pandemic on EyePoint’s business, the medical community and the global economy, and the impact of general business and economic conditions. More detailed information on these and additional factors that could affect EyePoint’s actual results are described in EyePoint’s filings with the SEC, including its

Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as revised or supplemented by its Quarterly Reports on Form 10-Q and other documents filed with the SEC. All forward-looking statements in this news release speak only as of the date of this news release. 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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