EyePoint Pharmaceuticals Announces First Patient Dosed in Phase 2 VERONA Clinical Trial of EYP-1901 for the Treatment of Diabetic Macular Edema

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WATERTOWN, Mass., Jan. 10, 2024 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious retinal diseases, today announced that the first patient has been dosed in the Phase 2 VERONA clinical trial of EYP-1901 for diabetic macular edema (DME). EYP-1901 is an investigational sustained delivery therapy containing vorolanib, a selective tyrosine kinase inhibitor formulated in bioerodible Durasert E.

“Dosing the first patient in the Phase 2 VERONA trial represents another significant milestone in advancing our mission to improve the lives of patients with serious retinal diseases. DME is a common sight-threatening complication of diabetes that can lead to severe vision loss. It represents the second diabetic eye disease indication that we are evaluating for potential treatment using EYP-1901,” said Jay Duker, M.D., Chief Executive Officer of EyePoint Pharmaceuticals. “There is a significant need for differentiated and longer-acting treatments for DME patients, as the current standard of care requires frequent intravitreal injections that are burdensome and can result in under-treatment. We are encouraged by the growing body of clinical data for EYP-1901 and we are optimistic that EYP-1901 has the potential to change the current treatment paradigm for DME with topline data expected in Q1 2025.”

Dr. Duker continued “We look forward to announcing additional milestones for the EYP-1901 clinical programs with topline data from the Phase 2 PAVIA clinical trial in non-proliferative diabetic retinopathy expected in the second quarter of 2024 and the initiation of the first Phase 3 pivotal trial in wet age-related macular degeneration (wet AMD) anticipated in the second half of 2024.”

VERONA is a randomized, controlled, single-masked, Phase 2 trial of EYP-1901 in DME patients previously treated with a standard-of-care anti-VEGF therapy. The three-arm trial is expected to enroll approximately 25 patients assigned to one of two intravitreal doses of EYP-1901 or an aflibercept control. The primary efficacy endpoint of the VERONA trial is time to first supplemental aflibercept injection up to 24 weeks based on established supplement criteria. Secondary endpoints include safety, change in best corrected visual acuity (BCVA), change in central subfield thickness (CST) as measured by optical coherence tomography (OCT), and change in diabetic retinopathy severity scale (DRSS) over time. More information about the trial is available at clinicaltrials.gov (identifier: NCT06099184).

About Diabetic Macular Edema

Diabetic macular edema (DME) is the leading cause of vision loss in people with type 1 and type 2 diabetes. DME results when damaged blood vessels leak fluid into the macula, the central portion of the retina responsible for the sharp vision needed for routine tasks such as driving or reading. This resulting retinal swelling can cause blurred vision and may lead to severe vision loss or even blindness. DME is a common form of sight-threatening retinopathy in people with diabetes, with approximately 28 million people afflicted worldwide. As the prevalence of diabetes continues to grow, an increased number of people will be affected by diabetic eye diseases such as DME. The current standard of care for patients experiencing DME include intravitreal injections of short-acting anti-VEGF biologics, corticosteroids, or laser photocoagulation which can become a burden on patients, caregivers, and physicians due to the longevity of the disease.

About EYP-1901

EYP-1901 is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. EYP-1901 delivers vorolanib, a selective and patent-protected tyrosine kinase inhibitor (TKI) formulated in 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 antifibrotic benefits. EYP-1901 is shipped and stored at ambient temperature and is administered with a standard intravitreal injection in the physician's office. EYP-1901 is immediately bioavailable, featuring an initial burst of drug, followed by near constant zero-order release kinetics for approximately nine months.

Positive data from both the Phase 1 DAVIO and Phase 2 DAVIO 2 clinical trials of EYP-1901 in wet AMD demonstrated clinically meaningful efficacy data with stable visual acuity and OCT, and a favorable safety profile. Further, the recent DAVIO 2 data demonstrated an impressive treatment burden reduction of approximately 88% at six-months, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection through up to 6 months. The data from the DAVIO 2 clinical trial supports the advancement of the wet AMD program to Phase 3 pivotal trials which are anticipated to initiate in the second half of 2024.

EYP-1901 is also being studied in non-proliferative diabetic retinopathy and diabetic macular edema. The Phase 2 PAVIA trial in NPDR is fully enrolled with topline data anticipated in the second quarter of 2024.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing 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, EYP-1901, is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert E ™. Additional pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, f/k/a AKB-9778, 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 for the localized treatment of all ophthalmic diseases outside of China, Macao, Hong Kong and Taiwan.

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 and EYP-2301; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration (wet AMD) and non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME); the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals including potential U.S. Food and Drug Administration (FDA) regulatory approval of EYP-1901 and EYP-2301; the success of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; the success of Durasert® as a drug delivery platform in FDA approved 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 impact of general business and economic conditions; 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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