EyePoint Pharmaceuticals Announces Two Presentations of Topline Data with Additional Subgroup Analyses from the Phase 2 DAVIO 2 Clinical Trial of EYP-1901 for the Treatment of Wet Age-Related Macular Degeneration

February 3, 2024

- *Subgroup analyses underscore favorable clinical profile and durability of EYP-1901*
- *Presentations highlight previously reported positive Phase 2 DAVIO 2 topline results showing all primary and secondary endpoints were met*
- *Results presented today at the Angiogenesis, Exudation, and Degeneration 2024 Virtual Meeting*

WATERTOWN, Mass., Feb. 03, 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 results from new subgroup analyses from the Phase 2 DAVIO 2 clinical trial of EYP-1901, an investigational sustained delivery maintenance treatment for wet age-related macular degeneration (wet AMD) combining vorolanib, a selective tyrosine kinase inhibitor with bioerodible Durasert E. These data are being presented in two sessions at the Angiogenesis, Exudation, and Degeneration 2024 Meeting held virtually today, February 3, 2024. The presenting speakers are Charles C. Wykoff, M.D., Ph.D., Director of Research, Retina Consultants of Texas, and Carl Regillo, M.D., FACS, Professor of Ophthalmology, Thomas Jefferson University.

“The findings from these subgroup analyses reinforce the highly favorable clinical profile of EYP-1901 and its potential to be a paradigm-altering maintenance treatment for patients with wet AMD,” said Jay Duker, M.D., Chief Executive Officer of EyePoint Pharmaceuticals. “The data demonstrated that in the subgroup analysis of patients that were supplement free up to 6 months, patients that received EYP-1901 demonstrated numerical superiority in change in best corrected visual acuity (BCVA) as well as anatomic stability compared to aflibercept. This result confirms that the positive visual and anatomical outcomes from our Phase 2 DAVIO 2 trial were driven by EYP-1901 and not by supplemental injections. We look forward to discussing plans for our upcoming Phase 3 trials, which we expect to initiate in the second half of 2024, at our end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA).”

The presented analyses of the data reveal:

- In the sub-group of patients who were supplement-free up to 6 months, the EYP-1901 groups demonstrated numerical superiority in change in BCVA along with strong anatomic control compared to the aflibercept control group. This result confirms that the positive topline data from the Phase 2 DAVIO 2 trial were driven by EYP-1901 and not by study eyes requiring supplemental injection.
- Visual and anatomical outcomes were not meaningfully influenced by differences in patient baseline BCVA, duration of wet AMD diagnosis, or historical treatment burden.
- EYP-1901outcomes are consistent and durable in a range of wet AMD patient types.

A second presentation also included the previously reported positive topline results of its Phase 2 DAVIO 2 trial of EYP-1901. The trial met its primary endpoint with both EYP-1901 doses demonstrating statistical non-inferiority change in best corrected visual acuity (BCVA) compared to aflibercept control and a favorable safety profile with no EYP-1901-related ocular or systemic serious adverse events (SAEs). The trial also achieved key secondary endpoints with both EYP-1901 doses, including an approximately 85% mean reduction in historical treatment burden, nearly two-thirds of eyes supplement-free up to six months and over 83% receiving only zero or one supplement up to six-months. Additionally, there was strong anatomical control in both EYP-1901 cohorts as measured by optical coherence tomography (OCT).

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of EYP-1901 in previously treated 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 standard intravitreal injection in the physician’s office, similar to current FDA approved anti-VEGF treatments. The primary non-inferiority efficacy endpoint is change in BCVA compared to the aflibercept control, approximately six-months after the EYP-1901 injection. Secondary endpoints include safety, change in CST as measured by OCT, the number of eyes that remain free of supplemental anti-VEGF injections, and number of aflibercept injections in each group. More information about the trial is available at clinicaltrials.gov (identifier: NCT05381948).

Phase 2 DAVIO 2 12-month results and the initiation of a Phase 3 trial in wet AMD are both expected in the second half of 2024. The Company remains on track to report additional clinical milestones with EYP-1901 this year with the readout of topline data from the Phase 2 PAVIA trial in non-proliferative diabetic retinopathy (NPDR) anticipated in the second quarter of 2024.

About Wet AMD

Age-related macular degeneration (AMD) is a leading cause of vision loss and irreversible blindness in people over the age of 60. Wet AMD is an advanced form of the condition that develops when abnormal blood vessels grow into the macular retina, leaking blood or fluid, and leading to potentially rapid and severe vision loss. Wet AMD is a lifelong disease that requires continuous treatment so that patients may maintain visual function. Although multiple treatments are now available, challenges still exist as the current standard-of-care is dosed on average every two months in the

United States under a treat-and-extend protocol, and these large molecule anti-VEGF treatments only target one pathology of the disease. This lifetime of frequent treatment represents a tremendous burden for patients, physicians, and the health care system, potentially leading to patient noncompliance and further vision loss.

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 may have 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 up to 88% at six-months, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection up to 6 months post-injection. 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 (NPDR) and diabetic macular edema (DME). The Phase 2 PAVIA trial in NPDR is fully enrolled with topline data anticipated in the second quarter of 2024. The Phase 2 VERONA trial in DME is enrolling with topline data expected in the first quarter of 2025.

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, 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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