EyePoint Pharmaceuticals Announces Positive Topline Data from the Phase 2 DAVIO 2 Trial of EYP-1901 in Wet AMD Achieving All Primary and Secondary Endpoints

December 4, 2023

– Both EYP-1901 cohorts demonstrated a statistically non-inferior change in BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2 mg and 3 mg dose at blended six-month endpoint –

– Positive safety profile continues with no EYP-1901-related ocular or systemic SAEs –

– Key secondary endpoints were achieved with both EYP-1901 doses. These include an over 80% reduction in treatment burden, with nearly two-thirds of eyes supplement-free up to six-months –

– Strong anatomical control in both EYP-1901 cohorts documented by optical coherence tomography (OCT) –

– Conference call to discuss the results to be held today, December 4, 2023 at 8:00 a.m. ET –

WATERTOWN, Mass., Dec. 04, 2023 (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 positive topline results of its Phase 2 DAVIO 2 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 ™. The clinical 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 over 80% reduction in treatment burden, nearly two-thirds of eyes supplement-free up to six months and over 80% receiving only zero or one supplement up to six-months. Additionally, there was strong anatomical control with both EYP-1901 cohorts as measured by optical coherence tomography (OCT).

"We are incredibly pleased by these highly positive Phase 2 results which underscore EYP-1901's potential as a paradigm-altering maintenance treatment for patients with wet AMD, with a positive safety profile. Since EYP-1901 achieved statistical non-inferiority to the aflibercept control in this trial there is potential for meaningfully lower sized and lower cost pivotal Phase 3 trials," said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. "I would like to thank the patients and the investigators who participated in the DAVIO 2 trial as well as our employees who helped advance us to this important milestone."

Dr. Duker continued, "the DAVIO 2 clinical trial was designed to support the initiation of Phase 3 clinical trials based on feedback received from the U.S. Food and Drug Administration (FDA) at a Type C meeting last year. The 32-week topline DAVIO 2 data strongly supports our planned Phase 3 non-inferiority design, consistent with the FDA's recent guidance for wet AMD clinical trials. We look forward to continuing our dialogue regarding our Phase 3 plans with the FDA as we prepare to initiate our first pivotal trial for wet AMD in the second half of 2024."

"These highly positive Phase 2 results are the result of years of hard work by the dedicated EyePoint team coupled with our proven Durasert technology which continues to demonstrate the benefit of zero order kinetics drug delivery. I look forward to initiation of Phase 3 and potentially bringing this innovative and much needed new drug to market for patients suffering from these blinding eye diseases," said Nancy Lurker, Executive Vice Chair of EyePoint Pharmaceuticals. "I want to congratulate the EyePoint team on the continued execution of this program."

DAVIO 2 topline interim results include:

- Both EYP-1901 doses (2mg and 3mg) achieved all primary and secondary endpoints.
- Statistical non-inferiority in change in BCVA (at a confidence interval of 95%) compared to aflibercept control, at weeks 28 and weeks 32 combined. The 2mg and 3mg doses were only -0.3 and -0.4 letters different, respectively, versus on-label aflibercept. The lower limit of the non-inferiority margin is defined as a -4.5 letters by the FDA with 5 letters representing one line on the eye chart.
- Continued positive safety and tolerability profile with no EYP-1901-related ocular or systemic SAEs.
- 89% and 85% reduction in treatment burden, respectively, for the 2mg and 3mg EYP-1901 doses.
- 65% and 64% of eyes were supplement free up to six-months, respectively, for the 2mg and 3mg doses of EYP-1901.
- Both EYP-1901 doses demonstrated strong anatomic control with OCT difference below 10 microns at week 32 compared to the aflibercept control.
- Patient discontinuation up to week 32 was low at 4%.

"Wet AMD is a prevalent and progressive lifetime disease. With frequent treatment, patients can maintain their visual acuity, but the unfortunate reality is that many patients end up undertreated due to the burden of dosing of the currently available, short-acting anti-VEGF therapies," said Carl Regillo, M.D., Chief of Retina Service at Wills Eye Hospital. "I am very encouraged by the data generated from both the Phase 1 DAVIO and Phase 2 DAVIO 2 trials with the latter showing essentially no difference in visual outcome at the blended six-month endpoint from a single injection of EYP-1901 compared to on-label, bimonthly aflibercept injections. Based on the meaningful reduction in treatment burden and supplement-free rates observed, along with the consistently favorable safety profile, I believe that EYP-1901 could be a paradigm shift in how patients with wet AMD are treated."

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 single 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).

EyePoint plans to present the DAVIO 2 dataset at Angiogenesis, Exudation, and Degeneration 2024 in February.

The Company remains on track to reach additional clinical milestones with EYP-1901 with the initiation of the Phase 2 VERONA trial in diabetic macular edema (DME) anticipated in the first quarter of 2024 and the readout of topline data from the Phase 2 PAVIA trial in non-proliferative diabetic retinopathy (NPDR) anticipated in the second quarter of 2024.

Conference Call and Webcast Information

EyePoint will host a conference call today, December 4, 2023 at 8:00 a.m. ET to discuss the results. To access the live conference call, please register at https://register.vevent.com/register/BI4c4d93355a394ea284131d7b537fd513. A live audio webcast of the event can be accessed via the Investors section of the Company website at www.eyepointpharma.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

About Wet AMD

Age-related Macular Degeneration (AMD) is a leading cause of irreversible blindness or vision loss 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 macula, leaking blood or fluid that leads to scarring of the macula and 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 blocker, blocking all VEGF isoforms. Vorolanib features reduced off-target binding and at clinically relevant doses does not inhibit Tie-2, a critical pathway associated with vascular stability, which may result in an improved efficacy. Further, in an in-vivo model of retinal detachment, vorolanib demonstrated neuroprotection, and potential antifibrotic benefits. EYP-1901 is shipped and stored at ambient temperature and is administered with a single intravitreal injection in the physician's office. EYP-1901 is immediately bioavailable, featuring an initial burst of drug, followed by near constant zero-order kinetic release 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 over 85% at six months, and over 80% of patients remained supplement-free or only received one supplemental anti-VEGF injection 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 (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 planned to initiate in the first quarter of 2024.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical-stage 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 (TKI) with Durasert E ™. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases. Additional pipeline programs include EYP-2301, a promising Tie-2 activator, razuprotafib, f/k/a AKB-9778, formulated in Durasert E™ to potentially improve outcomes in wet AMD and diabetic eye disease. The proven Durasert® drug delivery platform has been safely administered to over thousands of patient eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. For more information visit www.eyepointpharma.com.

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 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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