EyePoint Pharmaceuticals to Highlight DURAVYU™ (vorolanib intravitreal insert) Clinical and Regulatory Progress and Pipeline Innovation at R&D Day 2024

June 26, 2024

– Phase 3 trial design for the LUGANO and LUCIA pivotal non-inferiority trials of DURAVYU in wet AMD based on positive EOP2 meeting with FDA; on track for trial initiation in 2H 2024 –

– Positive twelve-month safety and efficacy data from Phase 2 DAVIO 2 clinical trial evaluating DURAVYU for the treatment of wet AMD reinforces potential as a sustained six-month maintenance therapy –

– Phase 2 trial of DURAVYU in diabetic macular edema (DME) fully enrolled –

– EyePoint to webcast its R&D Day event today at 8:00 a.m. ET –

WATERTOWN, Mass., June 26, 2024 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to help improve the lives of patients with serious retinal diseases, today announced the Company will highlight clinical and regulatory developments for its lead pipeline program, DURAVYU ™ (vorolanib intravitreal insert), formerly known as EYP-1901, its Durasert E ™ sustained drug delivery technology, and early-stage programs during EyePoint's R&D Day today, Wednesday, June 26, 2024, from 8:00 a.m. to 9:30 a.m. ET.

"EyePoint continues to pioneer the development of sustained-release drug delivery treatments for serious retinal diseases with DURAVYU ™, a potentially paradigm-shifting, best-in-class treatment for patients suffering from VEGF-mediated retinal diseases," said Jay Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. "We have a track record of strong execution, establishing the most robust dataset among sustained delivery TKI programs in wet age-related macular degeneration. We are excited to share the positive twelve-month DAVIO 2 clinical trial data for DURAVYU, as well as our Phase 3 clinical trial plans for wet age-related macular degeneration (wet AMD), with first patient dosing anticipated in the second half of this year. Importantly, our planned Phase 3 design includes redosing, consistent with expected commercial use. We believe DURAVYU and our earlier-stage programs, including EYP-2301, are potentially multi-billion-dollar product opportunities, and we remain laser focused on advancing our mission of improving patient vision with innovative treatment options."

R&D Day will feature commentary from EyePoint's management team as well as key opinion leader (KOL) guest speakers, Carl D. Regillo, M.D., FACS, Professor of Ophthalmology at Thomas Jefferson University, Chief of Retina Service at Wills Eye Hospital, Founder of Wills Eye Clinical Retina Research Unit in Philadelphia, and Partner at Mid Atlantic Retina and Yasha S. Modi, M.D., Associate Professor of Vitreoretinal Surgery, Retinal Disease and Uveitis at New York University and Director of Teleretina.

R&D Day Highlights:

- **Phase 3 plans for DURAVYU ™ in wet AMD, including key design elements of the Phase 3 LUGANO and LUCIA pivotal trials**
  - Alignment on pathway to approval with U.S. Food and Drug Administration (FDA) based on positive End of Phase 2 meeting for two non-inferiority trials, 6-month redosing of DURAVYU and sham for masking with a one-year endpoint.
  - Each trial is expected to enroll approximately 400 patients with active wet AMD, including previously treated and treatment naïve patients, randomly assigned to either a 2.7mg dose of DURAVYU or an on-label aflibercept control. All patients to receive three monthly loading doses of aflibercept prior to DURAVYU with randomization occurring on Day 1.
  - The LUGANO (US) trial remains on track to initiate in 2H 2024 with LUCIA (US/ex-US) to follow.
- **Positive twelve-month safety and efficacy data from the Phase 2 DAVIO 2 clinical trial evaluating DURAVYU ™ for the treatment of wet AMD**
  - **Favorable safety profile –** No DURAVYU related ocular or systemic SAEs
  - **Best corrected visual acuity (BCVA)** – Statistically significant visual acuity outcomes with both DURAVYU arms change in visual acuity nearly identical to aflibercept control arm through 12 months after a single injection of DURAVYU
  - **Central Subfield Thickness (CST)** – Strong anatomical control through 12 months after a single injection of DURAVYU
  - **Supplement Free** – After a single injection of DURAVYU, approximately half of the treated study eyes were anti-VEGF supplement free, while 22% of the eyes in the aflibercept control arm were administered a supplement despite these control eyes receiving mandated bi-monthly injections through 12 months
- **The VERONA trial, a Phase 2 trial of DURAVYU ™ in diabetic macular edema (DME) patients has completed**

enrollment with 27 patients assigned to one of two intravitreal doses of DURAVYU or an aflibercept control. To date, DURAVYU is well-tolerated with no reported drug-related ocular or systemic serious adverse events in this trial.

“We are very encouraged with the excellent safety and efficacy results from our Phase 2 DAVIO 2 trial. We believe there remains a significant opportunity for a safe and effective sustained delivery maintenance treatment in wet AMD, and we believe the DAVIO 2 trial data reinforces the potential for DURAVYU to maintain a majority of patients with active disease with no supplemental anti-VEGF therapy for six months or longer," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint Pharmaceuticals. "We look forward to enrolling patients in the Phase 3 LUGANO clinical trial for DURAVYU in wet AMD later this year, and we believe that with these DAVIO 2 results and our real-world-based pivotal trial design in-hand, we are in an excellent position to advance this innovative therapy and improve the lives of patients suffering from serious retinal diseases."

R&D Day Webcast Information

To access the live conference call, please register at https://register.vevent.com/register/BI10e9bca3aca34595a46c9a0e08ef92da. A live webcast and subsequent archived replay of the presentation may be accessed via the Investors section of the Company website at www.eyepointpharma.com. The replay will be available for 90 days after the event.

About the Phase 2 DAVIO 2 and Phase 3 LUGANO and LUCIA Clinical Trials

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of DURAVYU ™ 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 DURAVYU (approximately 2 mg or 3 mg) or an aflibercept control. DURAVYU 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 DURAVYU injection. Secondary endpoints include safety, change in CST as measured by optical coherence tomography (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 anticipates that the first patient in the Phase 3 LUGANO clinical trial of DURAVYU for wet AMD will be dosed in 2H 2024 and the LUCIA trial to follow. The pivotal trials are expected to enroll approximately 400 patients with active wet AMD each, including both previously treated and treatment naïve patients, randomly assigned to 2.7mg of DURAVYU versus an on-label aflibercept control. DURAVYU is delivered with a single intravitreal injection in the physician's office, similar to current FDA approved anti-VEGF treatments. The primary efficacy endpoint of the LUGANO and LUCIA trials is non-inferiority to the aflibercept control, as measured by change in BCVA twelve-months after two DURAVYU injections that will be administered six-months apart. Secondary efficacy endpoints include change in CST as measured by OCT, time to first supplemental anti-VEGF, reduction in treatment burden and safety.

About DURAVYU ™

DURAVYU ™, previously known as EYP-1901, is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. DURAVYU 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. DURAVYU is shipped and stored at ambient temperature and is administered with a standard intravitreal injection in the physician's office. DURAVYU is also immediately bioavailable with zero-order release kinetics release for approximately nine months.

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, DURAVYU ™ (previously known as 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™. 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, a Betta Pharmaceuticals affiliate, for the localized treatment of all ophthalmic diseases outside of China, Macao, Hong Kong and Taiwan.

DURAVYU ™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.

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 statements about the sufficiency of our existing cash resources through topline data for Phase 3 clinical trials for EYP-1901 (DURAVYU ™) in wet AMD; our expectations regarding the timing and clinical development of our product candidates, including DURAVYU and EYP-2301; the potential for DURAVYU 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 DURAVYU and EYP-2301; the success of current and future license agreements; our dependence on contract research organizations, 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.

Investors:
Christina Tartaglia
Precision AQ (formerly Stern IR)
Direct: 212-698-8700
christina.tartaglia@sternir.com

Media Contact:
Amy Phillips
Green Room Communications
Direct: 412-327-9499
aphillips@greenroompr.com

Source: EyePoint Pharmaceuticals, Inc.