EyePoint Pharmaceuticals Announces Positive Interim 16-Week Data for Ongoing Phase 2 VERONA Clinical Trial of DURAVYU™ for Diabetic Macular Edema

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- DURAVYU 2.7mg demonstrated an early and sustained improvement in BCVA with a gain of +8.9 letters compared to baseline -

– DURAVYU 2.7mg demonstrated an early and sustained anatomical improvement mirroring BCVA results with a 68 micron reduction in CST -

– Favorable safety profile continues with no DURAVYU-related ocular or systemic SAEs to date –

– Full topline data anticipated in Q1 2025 –

WATERTOWN, Mass., Oct. 28, 2024 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases, today announced positive interim 16-week data for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU, an investigational sustained delivery therapy delivering patent-protected vorolanib, a selective tyrosine kinase inhibitor formulated in proprietary bioerodible Durasert E™, for patients with diabetic macular edema (DME). DURAVYU 2.7mg demonstrated an early, sustained, and clinically meaningful improvement in best-corrected visual acuity (BCVA) and anatomical control versus the aflibercept control arm. A favorable safety and tolerability profile continued for both DURAVYU arms. The 2.7mg dose is also being evaluated in the Phase 3 pivotal trials for wet AMD. The Company expects to report the full topline results in the first quarter of 2025, once all patients complete the trial.

“We are encouraged and excited by these highly positive interim results demonstrating clinically meaningful functional and concomitant structural improvement with a continued favorable safety profile of DURAVYU,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. “DME is a prevalent disease with a significant need for more durable treatments. The interim data from the VERONA trial demonstrates that after a single DURAVYU 2.7mg treatment there was a meaningful, early and maintained improvement in BCVA paired with strong anatomical improvement in retinal thickness, demonstrating the potential for DURAVYU in DME as a sustained delivery therapy. One of the most notable aspects of these data is that both DURAVYU doses showed an immediate benefit over aflibercept control in both BCVA and CST. We believe these compelling interim results support DURAVYU’s potential to advance to non-inferiority pivotal trials in DME. With pivotal wet AMD clinical trials underway and promising DME interim data, DURAVYU has the potential to be the first sustained release therapy to market in two significant indications.”

Phase 2 VERONA interim 16-week results as of October 1, 2024 data cut-off include:

- All patients (n=27) have completed the week 16 visit.
- DURAVYU 2.7mg demonstrated an early and sustained improvement in both BCVA and CST (central subfield thickness) as measured by optical coherence tomography (OCT).
    - BCVA improved +8.9 letters versus +3.2 letters for aflibercept control compared to baseline.
    - CST improved 68.1 microns versus 30.5 microns for aflibercept control compared to baseline.
- Visual and anatomical gains were observed at Week 4 demonstrating the immediate bioavailability of DURAVYU.
- Positive trend in BCVA and anatomy continued for patients that have reached the Week 24 visit.
- Continued positive safety and tolerability profile with no DURAVYU-related ocular or systemic serious adverse events. Additionally, there were no cases of:
    - Endophthalmitis
    - Retinal vasculitis (occlusive or non-occlusive)
    - Insert migration to the anterior chamber
    - Intraocular inflammation (IOI)
- 82% of eyes in the DURAVYU 2.7mg arm were supplement-free versus 50% in the aflibercept control arm at 16 weeks.

“DME is a sight-threatening complication of diabetes that can lead to severe visual loss and eventual blindness,” said Charles Wykoff, M.D., Ph.D., Director of Research, Retina Consultants of Texas and Co-Chair of EyePoint’s Scientific Advisory Board. “There remains a significant need for differentiated and longer-acting treatments, as the current standard of care involves frequent intravitreal injections that can be a burden and have been associated with under-treatment. The interim data from the Phase 2 VERONA trial suggests promising activity in patients with active DME versus aflibercept alone and a favorable safety profile. These results support the potential for DURAVYU to bring substantial value to patients through stable, durable disease control.”

“Reducing the treatment burden in patients with DME is a critical unmet need,” said Adam Gerstenblith, M.D., a principal investigator in the VERONA clinical trial and vitreoretinal surgeon at Mid Atlantic Retina Specialists. “As a clinician dedicated to advancing retinal care, I am encouraged by the interim clinical data demonstrating the potential for DURAVYU 2.7mg to extend treatment intervals while improving vision without sacrificing anatomy. The VERONA trial is an important step in the pursuit of treatment options for patients that are safe and durable, and I am pleased to be participating in research that has the potential to shift the treatment paradigm in DME and ultimately improve patient outcomes.”

VERONA is a randomized, controlled, single-masked, open label Phase 2 trial of DURAVYU in DME patients previously treated with a standard-of-care anti-VEGF therapy. The trial enrolled 27 patients assigned to one of two intravitreal doses of DURAVYU (1.3mg or 2.7mg) or 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. Key secondary endpoints include safety, mean change in best corrected visual acuity (BCVA), mean 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 DURAVYU ™

DURAVYU™, f/k/a EYP-1901, is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. DURAVYU delivers vorolanib, a potent, selective and patent-protected tyrosine kinase inhibitor (TKI) as 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 as it also blocks PDGF. DURAVYU is shipped and stored at ambient temperature and is administered with a standard intravitreal injection in the physician's office. DURAVYU is immediately bioavailable with zero-order kinetics release for up to nine months.

Positive data from both the Phase 1 DAVIO and Phase 2 DAVIO 2 clinical trials of DURAVYU in wet AMD demonstrated clinically meaningful efficacy data with stable visual acuity and CST and a favorable safety profile. Further, data from DAVIO 2 demonstrated an impressive treatment burden reduction of approximately 88% at eight months, six months after treatment with DURAVYU, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection through up to eight months, six months after treatment with DURAVYU. The data from the DAVIO 2 clinical trial supported the advancement of the wet AMD program and the initiation of the Phase 3 LUGANO trial, with the LUCIA pivotal trial to follow by year end 2024.

DURAVYU is also currently being studied in the Phase 2 VERONA trial for diabetic macular edema (DME). Full topline data is expected in the first quarter of 2025.

About EyePoint Pharmaceuticals

EyePoint (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative 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 ™ (f/k/a EYP-1901), is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with bioerodible Durasert E ™. DURAVYU is presently in Phase 3 global, pivotal clinical trials as a sustained delivery treatment for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States, and in a Phase 2 clinical trial in diabetic macular edema (DME). EyePoint expects full topline data from the Phase 2 clinical trial in DME in Q1 2025 and topline data from both Phase 3 pivotal trials in wet AMD in 2026.

Pipeline programs include EYP-2301, a 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 our expectations regarding the timing and clinical development and potential of DURAVYU in DME and wet AMD, including our expectations regarding the announcement of full topline data from the VERONA trial in the first quarter of 2025 and initiation of the LUGANO trial and the LUCIA trial; the belief that the interim results from the VERONA trial support DURAVYU's potential to advance to non-inferiority pivotal trials; our beliefs and expectations regarding the anticipated full results from the VERONA trial; the potential for DURAVYU 2.7mg to extend treatment intervals while improving vision without sacrificing anatomy; the potential for DURAVYU to provide an immediate benefit over aflibercept control in both BCVA and CST; our optimism that that DURAVYU has the potential to shift the treatment paradigm in DME and improve patient outcomes; our expectations regarding clinical development of our other product candidates, including EYP-2301; our business strategies and objectives; 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, these risks and uncertainties include the timing, progress and results of the company's clinical development activities; uncertainties and delays relating to the design, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; the company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the risk that results of clinical trials may not be predictive of future results, and interim and

preliminary data are subject to further analysis and may change as more data becomes available; unexpected safety or efficacy data observed during clinical trials; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for approval of the company's product candidates; changes in the regulatory environment; changes in expected or existing competition; the success of current and future license agreements; our dependence on contract research organizations, and other outside vendors and service providers; product liability; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; delays, interruptions or failures in the manufacture and supply of our product candidates; the availability of and the need for additional financing; the company's ability to obtain additional funding to support its clinical development programs; uncertainties regarding the timing and results of the August 2022 subpoena from the U.S. Attorney's Office for the District of Massachusetts; uncertainties regarding the FDA warning letter pertaining to the company's Watertown, MA manufacturing facility; 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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