EyePoint Announces Positive Six-Month Results for the Phase 2 VERONA Clinical Trial of DURAVYU™ for Diabetic Macular Edema Meeting Primary and Secondary Endpoints

Feb 5, 2025

- Primary endpoint achieved by both DURAVYU doses (1.34mg and 2.7mg) with extended time to first supplemental injection versus aflibercept control –

- DURAVYU 2.7mg demonstrated an early and sustained improvement in BCVA with a 24-week gain of +7.1 letters and anatomical improvement of 76 microns reduction in CST paired with reduction in treatment burden of two-thirds

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

– Phase 3 non-inferiority pivotal program initiation anticipated by the end of 2025 –

– Conference call to be held today, February 5, 2025 at 8:00 a.m. ET –

WATERTOWN, Mass., Feb. 05, 2025 (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 six-month results for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU™ (vorolanib intravitreal insert), an investigational sustained delivery therapy delivering patent-protected vorolanib, a selective tyrosine kinase inhibitor (TKI) formulated in proprietary bioerodible Durasert E™. The clinical trial met its primary endpoint with extended time to first supplemental injection compared to aflibercept control for both DURAVYU doses. The trial also demonstrated clinically meaningful outcomes including continued safety with no DURAVYU-related ocular or systemic serious adverse events (SAEs) and an early and sustained improvement in vision and anatomical control. DURAVYU 2.7mg demonstrated a +7.1 letter BCVA gain and 76-micron CST reduction at week 24, with a supplement-free rate of 73% versus 50% for eyes treated with aflibercept. These positive Phase 2 VERONA results add to a robust dataset across another key indication demonstrating the best-in-class potential for DURAVYU in serious retinal diseases.

“We are extremely pleased to report these highly positive VERONA results that demonstrate 2.7mg DURAVYU immediately and meaningfully improves both visual acuity and anatomy in DME patients with a superior dosing interval and excellent safety. This underscores the potential of DURAVYU to be a best-in-class treatment for patients,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. “DME is the leading cause of vision loss in working age adults and the second largest market in retinal diseases after wet age-related macular degeneration (wet AMD). The data from the VERONA trial demonstrate that after a single DURAVYU 2.7mg treatment there was an early and maintained improvement in both BCVA and retinal thickening as measured by OCT throughout the six-month trial, demonstrating the differentiated profile of DURAVYU with immediate bioavailability and zero order kinetics drug delivery. Importantly, the favorable safety and tolerability profile of DURAVYU continued with no DURAVYU-related ocular or systemic serious adverse events. These compelling results support a noninferiority pivotal program in DME, and we plan to meet with the FDA in the second quarter for potential initiation of a Phase 3 clinical trial later in 2025. With ongoing pivotal trials in wet AMD on track to read-out in 2026 and positive efficacy and safety data across multiple Phase 2 clinical trials, DURAVYU is well-positioned to become a potential blockbuster franchise.”

Phase 2 VERONA results as of January 16, 2025 data cut-off include:

- Both DURAVYU doses (1.34 mg and 2.7mg) met the primary endpoint of extended time to first supplemental injection versus aflibercept control.
- DURAVYU 2.7mg demonstrated an early and sustained improvement in both best corrected visual acuity (BCVA) and central subfield thickness (CST) as measured by optical coherence tomography (OCT).
    - BCVA improved +7.1 letters compared to baseline.
    - CST improved 75.9 microns compared to baseline representing 74% more drying in DURAVYU eyes versus aflibercept control.
- Visual and anatomical gains were observed at Week 4 demonstrating the immediate bioavailability of DURAVYU.
- 73% of eyes in the DURAVYU 2.7mg arm were supplement-free versus 50% in the aflibercept control arm up to week 24 underscoring that the positive efficacy results were driven by treatment with DURAVYU and not supplemental injections.
- Over two-thirds reduction in treatment burden for 2.7mg dose.

- DURAVYU favorable safety profile continues:
  - No DURAVYU-related ocular or systemic serious adverse events reported
  - No cases of:
    - Impaired vision
    - Endophthalmitis
    - Retinal vasculitis (occlusive or non-occlusive)
    - Insert migration
    - Intraocular inflammation (IOI)

“DME is a prevalent disease with a significant need for more durable treatments,” said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer. “The data from the Phase 2 VERONA trial demonstrated that within four weeks, eyes treated with DURAVYU had a significant benefit for patients with DME, both visually and anatomically. The magnitude of these results gives us confidence moving forward into a Phase 3 noninferiority program with a differentiated treatment for patients with DME who need effective, safe and durable treatment options. We would like to thank the patients, investigators and their staff for participating in the trial, and we look forward to working with regulatory agencies to discuss next steps as we work to advance this innovative therapy and improve the lives of patients suffering from serious retinal diseases.”

“The diabetes epidemic and the associated increase in patients with DME has resulted in a significant burden to patients and the healthcare system,” said Carl Regillo, M.D., FACS, Chief of Retina Service at Wills Eye Hospital and Co-Chair of EyePoint’s SAB. “The number of diabetic retinopathy patients is predicted to reach 16 million by 2050, and diabetes-related vision loss is expected to cost 500 million US dollars annually. The average patient with DME is working age and requires burdensome monthly injections that can result in missed visits and chronic undertreatment. This can lead to irreparable vision loss and potential blindness. I am very encouraged by the Phase 2 VERONA data demonstrating the ability to improve vision and anatomy while maintaining a favorable safety and tolerability profile. Additionally, DURAVYU features zero order kinetics release, so the VEGF receptors remain blocked for at least six months enabling the ability to extend dosing intervals while maintaining the patient’s vision. This feature will be important in the DME population, giving patients and physicians a durable treatment option. Based on these meaningful Phase 2 results, I believe DURAVYU demonstrates the ability to fundamentally alter the treatment paradigm in DME, and if approved, has the potential for significant adoption among retina specialists.”

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 (1.34mg 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).

The 16-week interim data will be presented at Angiogenesis, Exudation, and Degeneration 2025 in February and the full six-month data at an upcoming medical meeting.

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 includes 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 sustained-delivery maintenance treatment for patients suffering from chronic VEGF-mediated retinal diseases. DURAVYU delivers vorolanib, a differentiated and patent-protected tyrosine kinase inhibitor (TKI), as a solid bioerodible insert using EyePoint’s proprietary and best-in-class bioerodible Durasert E ™ technology. Vorolanib brings a new mechanism of action to the treatment of VEGF-mediated retinal diseases as a potent and highly selective pan-VEGF receptor inhibitor. Benefits of this new mechanistic approach include the demonstration of neuroprotection in an *in vivo* model of retinal detachment, as well as blockage of PDGF, which may have potential antifibrotic benefits.

DURAVYU has established a robust safety and efficacy profile with the largest TKI intravitreal (IVT) trial dataset in wet AMD to-date. Positive data from Phase 1 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. Data from DAVIO 2 demonstrated an impressive treatment burden reduction of approximately 88% six months after treatment with DURAVYU, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection. DURAVYU is actively enrolling in two ongoing global Phase 3 clinical trials, LUGANO and LUCIA, in wet AMD. The pivotal programs are evaluating re-dosing of DURAVYU compared to non-inferiority with standard-of-care, with the goal of providing the retina community valuable insight into ‘real-world’ usage of

DURAVYU.

DURAVYU is also currently being studied for the treatment of diabetic macular edema (DME). The Phase 2 VERONA trial met the primary endpoint and demonstrated an immediate and sustained improvement in vision and anatomy, a continued favorable safety and tolerability profile with superior dosing intervals to standard of care. These positive Phase 2 results support the advancement of the DME program to a Phase 3 pivotal program which is anticipated to be initiated by the end of 2025.

About EyePoint

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 ™ 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 ™. Supported by robust safety and efficacy data to date, DURAVYU is presently in Phase 3 global, pivotal clinical trials 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). Based on positive Phase 2 results from the VERONA clinical trial in DME, EyePoint anticipates initiation of a Phase 3 pivotal program by the end of 2025 with 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 in multiple disease indications. 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 VERONA trial following our announcement of full topline data and the progress of our ongoing LUGANO and LUCIA trials; our beliefs and expectations that the full topline results from the VERONA trial support DURAVYU's potential to advance to non-inferiority pivotal trials; 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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