EyePoint Pharmaceuticals Presents Preliminary Safety Data from Phase 1 DAVIO Trial and YUTIQ® CALM Registry Study at American Society of Retina Specialists (ASRS) 39th Annual Meeting

October 12, 2021

– 3-month safety data from DAVIO trial continues to demonstrate EYP-1901 is well-tolerated in eyes with wet AMD –

– YUTIQ® CALM registry study collecting real-world data on patients with fluocinolone acetonide intravitreal (FAi) implant 0.18 mg is ongoing –

WATERTOWN, Mass., Oct. 12, 2021 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced positive interim safety data from its Phase 1 clinical trial of EYP-1901, a potential twice-yearly sustained delivery anti-VEGF treatment targeting wet age-related macular degeneration (wet AMD), and preliminary results from YUTIQ® CALM, a real-world registry study of the fluocinolone acetonide intravitreal (FAi) implant 0.18 mg in chronic noninfectious posterior uveitis. The two studies were presented in a Paper-On-Demand and an ePoster Presentation, respectively, at the American Society of Retina Specialists (ASRS) 39th Annual Meeting held October 8 – 12, 2021.

"We are excited to report that preliminary 3-month safety data for all patients from our ongoing DAVIO trial of EYP-1901 continues to demonstrate an excellent safety profile with no serious ocular or systemic adverse events reported to date," said Nancy Lurker, CEO of EyePoint Pharmaceuticals. "These results support EYP-1901's potential to provide wet AMD patients with a safe, effective and long-term therapeutic option. We are also pleased to present preliminary results from the CALM registry study, which allows us to better understand the patients we serve, and, subsequently, how we can ensure that YUTIQ, using EyePoint's proprietary Durasert ® technology, remains the most effective and innovative solution for our patients' unmet needs."

Summaries of the ASRS presentations are as follows:

Title: Initial Safety Results of the DAVIO Trial: An Open Label, Dose Escalation Phase 1 Study of EYP-1901, a Tyrosine Kinase Inhibitor (TKI) in Subjects with Wet AMD
Presenters: Vrinda S. Hershberger, MD, PhD; David R. Lally, MD; Mark R. Barakat, MD and Dario A. Paggiarino, MD
Type: On-Demand Poster Presentation

The Phase 1 DAVIO open-label, dose escalation trial clinical trial of EYP-1901 enrolled 17 wet AMD patients across three dose cohorts. The study is ongoing, and all patients were previously treated with standard of care anti-VEGF therapies. Key safety observations through at least 3-months post-dosing for all patients include that no serious adverse events (SAEs), ocular or systemic, were reported. 21 ocular adverse events (AEs) were reported, all mild (19) to moderate (2) in severity, and there have been no reported AEs related to significant intraocular inflammation, best corrected visual acuity (BCVA) reduction, or elevation of intra-ocular pressure (IOP). No events of endophthalmitis, retinal detachment, or migration into the anterior chamber have been reported to date.

EyePoint plans to release interim efficacy results once the study has sufficient follow-up data for all dose cohorts later in the fourth quarter of this year.

Title: YUTIQ® CALM: A Real-World Registry Study of the Fluocinolone Acetonide Intravitreal Implant 0.18 Mg in Chronic Noninfectious Posterior Uveitis
Presenters: Ankur Shah, M.D. and Rene Choi, M.D.
Type: ePoster Presentation

The ongoing YUTIQ CALM real-world registry study is collecting data on patients who have received the fluocinolone acetonide intravitreal implant 0.18 mg. This study included patients of 18 years of age and older with a diagnosis of chronic noninfectious uveitis affecting the posterior segment and no contradictions to the FAi. Baseline and follow-up data are collected retrospectively and include central subfield thickness (measured via optical coherence tomography); best-corrected visual acuity; presence of inflammation; use of concomitant anti-inflammatory medications; and incidence of adverse events. Interim baseline data on patients in the registry as of August 2021 reveal that patients feature a substantial duration of uveitis (mean 57 months, or about 4.75 years), a variety of etiologies (largely unknown) and previous treatments (most often topical, intraocular and systemic corticosteroids and immunomodulatory drugs) in their medical history. Ocular characteristics include the presence of macular edema (mean CST 353.56 microns), relatively poor BCVA (mean 55.15 ETDRS letters) and an IOP generally in normal range (mean 13.35 mmHg). Most patients had relatively controlled intraocular inflammation as measured by AC cell and vitreous haze.

About EYP-1901

EYP-1901 is a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment for wet age-related macular degeneration. EYP-1901 combines a bioerodible formulation of EyePoint's proprietary Durasert ® sustained release technology with vorolanib, a tyrosine kinase inhibitor. Vorolanib provided clear efficacy signals in two prior human trials in wet AMD as an orally delivered therapy with no significant ocular adverse events. Preclinical studies of EYP-1901 have shown anti-VEGF activity in disease models of ocular neovascularization and no serious safety issues were observed. EYP-1901 is initially being developed as a treatment for wet AMD, with the potential for additional indications in diabetic retinopathy and retinal vein occlusion.

About YUTIQ®

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye, and was approved by the FDA on October 12, 2018. A link to the full product label is available on the YUTIQ website at: https://yutiq.com/downloads/US-YUT-2100035%20YUTIQ%20Prescribing%20Information-2021.pdf.

About Chronic Non-infectious Uveitis Affecting the Posterior Segment of the Eye

Non-infectious posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which affects people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior segment uveitis is estimated to affect between 55,000 - 120,000 people resulting in approximately 30,000 cases of blindness, making it the third leading cause of blindness in the U.S. Today, patients with posterior uveitis are typically treated with either local steroid injections, with limited duration of effect, or systemic steroids, but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer.

About EyePoint Pharmaceuticals, Inc.

EyePoint Pharmaceuticals (Nasdaq:EYPT) is a pharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary Durasert® technology for sustained intraocular drug delivery including EYP-1901, a potential twice-yearly intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. The Company has two commercial products: YUTIQ®, for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, for the treatment of postoperative inflammation following ocular surgery. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. To learn more about the Company, please visit www.eyepointpharma.com and connect on Twitter and LinkedIn.

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 anticipated use of proceeds for the proposed 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 our expectations regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel twice-yearly treatment for serious eye diseases, including wet age-related macular degeneration, diabetic retinopathy and retinal vein occlusion; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued impact of the COVID-19 pandemic on EyePoint’s business, the medical community and the global economy and the impact of general business and economic conditions; our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for YUTIQ and DEXYCU; the development of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; the success of current and future license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; termination or breach of current license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; 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. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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