EyePoint Pharmaceuticals Announces Positive 12-Month Safety and Efficacy Data from Phase 1 DAVIO Clinical Trial Evaluating EYP-1901 for the Treatment of Wet AMD

July 15, 2022

Data reinforces strong safety and efficacy for EYP-1901 as a potential six-month maintenance treatment for previously treated wet AMD

No dose limiting toxicities, no ocular serious adverse events (SAEs) and no drug-related systemic SAEs observed

Stable visual acuity and optical coherence tomography observed from a single treatment

Phase 2 clinical trial (DAVIO2) in wet AMD patient dosing anticipated in Q3 2022

WATERTOWN, Mass., July 15, 2022 /PRNewswire/ -- 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 12-month data from the Phase 1 "Durasert® and Vorolanib in Ophthalmology" (DAVIO) clinical trial evaluating EYP-1901, a sustained delivery anti-vascular endothelial growth factor (anti-VEGF) therapy targeting wet age-related macular degeneration (wet AMD) as a potential every six-month treatment. These data are being presented today at the American Society of Retina Specialists (ASRS) 2022 Annual Meeting by Rishi Singh, M.D., Staff Physician, Cleveland Clinic Florida, President – Cleveland Clinic Martin Hospitals.

"The final 12-month results from the DAVIO clinical trial highlight EYP-1901's continued positive safety and efficacy profile with promising durability as a potential every six-month maintenance therapy for previously treated wet AMD," said Rishi Singh, M.D., a member of EyePoint's Scientific Advisory Board. "We are grateful to the patients, investigators and site staff who participated in the Phase 1 DAVIO trial."

"We are extremely pleased with the excellent safety and efficacy results from our Phase 1 DAVIO trial. There remains a significant opportunity for a safe and effective sustained delivery maintenance treatment in wet AMD, and the DAVIO trial demonstrates that EYP-1901 has the potential to maintain a majority of patients for up to six months with no supplemental anti-VEGF therapy," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "We look forward to beginning to dose patients in the Phase 2 DAVIO2 clinical trial for EYP-1901 in wet AMD and anticipate top line data in the second half of 2023."

The final twelve-month data presented from the Phase 1 DAVIO clinical trial showed no reports of ocular SAEs or drug-related systemic SAEs. There were no reported events of vitreous floaters, endophthalmitis, retinal detachment, implant migration in the anterior chamber, retinal vasculitis, posterior segment inflammation, or retinal vascular occlusive events. Additionally, updated data from the twelve-month follow-up confirm stable best corrected visual acuity (BCVA) (-4.12 ETDRS letters), stable central subfield thickness (CST) on optical coherence tomography (OCT) (-2.76 µm), and an expected late increase in supplemental anti-VEGF therapy given the insert's expected drug depletion, with 35% of eyes supplement free up to twelve months versus 53% supplement free up to six months. Additionally, there continued to be positive treatment burden reduction of 74% at twelve months versus 79% at six-months.

EyePoint anticipates that the first patient in the twelve-month, randomized, controlled Phase 2 clinical trial (DAVIO2) of EYP-1901 for wet AMD will be dosed in Q3 2022. The trial is expected to enroll approximately 150 wet AMD patients previously treated with a standard-of-care anti-VEGF therapy and randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg) versus an on-label 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 efficacy endpoint of the DAVIO2 trial is non-inferiority to the aflibercept control, as measured by change in BCVA six-months after the EYP-1901 injection. Secondary efficacy endpoints include change in CST as measured by OCT, time to first supplemental anti-VEGF, and safety. More information about the study is available at clinicaltrials.gov (identifier: NCT05381948).

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment, initially in wet age-related macular degeneration (wet AMD) combining a bioerodible formulation of EyePoint's proprietary Durasert® delivery technology with vorolanib, a tyrosine kinase inhibitor. Positive twelve-month safety and efficacy data from the Phase 1 DAVIO clinical trial of EYP-1901 showed no reports of ocular or drug-related systemic serious adverse events and no dose limiting toxicities with stable visual acuity and OCT. Further, 53% of eyes did not require supplemental anti-VEGF injections up to six months following a single dose of EYP-1901. A Phase 2 trial for wet AMD (DAVIO2) is expected in Q3 2022 and Phase 2 studies are planned for non-proliferative diabetic retinopathy and diabetic macular edema in 2H 2022 and 2023, respectively. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

About Wet AMD

Age-related macular degeneration (AMD) impacts as many as 11 million Americans. About 15% of those affected have neovascular or wet AMD - the hallmark of which is fluid and bleeding in the center of the retina, which may lead to irreversible vision loss. The majority of patients with wet AMD require intravitreal injections every month or two to control the disease. This intense treatment regimen represents an ongoing challenge for patients,

caregivers, and physicians.

About EyePoint Pharmaceuticals

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, an investigational sustained delivery intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. The proven Durasert drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products, including YUTIQ® for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which is currently marketed by the Company. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

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 uncertainties regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a sustained delivery intravitreal anti-VEGF treatment for serious eye diseases, including wet age-related macular degeneration; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the success of current and future license agreements; 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 our commercialized products, YUTIQ® and DEXYCU®; market acceptance of our 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 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. More detailed information on these and additional factors that could affect EyePoint's actual results are described in EyePoint's filings with the SEC, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as revised or supplemented by its Quarterly Reports on Form 10-Q and other documents filed with the SEC. All forward-looking statements in this news release speak only as of the date of this news release. 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
Stern IR
Direct: 212-698-8700
christina.tartaglia@sternir.com

Media Contact

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

View original content to download multimedia:https://www.prnewswire.com/news-releases/eyepoint-pharmaceuticals-announces-positive-12-month-safety-and-efficacy-data-from-phase-1-davio-clinical-trial-evaluating-eyp-1901-for-the-treatment-of-wet-amd-301587236.html

SOURCE EyePoint Pharmaceuticals, Inc.