

EyePoint Pharmaceuticals Announces First Patient Dosed in Phase 2 DAVIO 2 Clinical Trial of EYP-1901 for the Maintenance Treatment of Wet AMD

August 1, 2022

-Topline data expected in the second half of 2023-

WATERTOWN, Mass., Aug. 1, 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 that the first patient has been dosed in the Phase 2 "Durasert[®] and Vorolanib in Ophthalmology 2" (DAVIO 2) clinical trial of EYP-1901, an investigational sustained delivery anti-vascular endothelial growth factor (anti-VEGF) treatment for wet age-related macular degeneration (wet AMD).



"We are very pleased to announce the initiation of the Phase 2 DAVIO 2 clinical trial of EYP-1901 for wet AMD. Using a 'Treat to Maintain' therapeutic approach, EYP-1901 has the potential to transform the wet AMD treatment landscape by sustaining a majority of patients up to six months without supplemental anti-VEGF treatment, thereby greatly reducing the treatment burden," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "We are encouraged by the safety and efficacy results from our Phase 1 DAVIO trial, including no reports of ocular or drug related systemic serious adverse events and strong durability data with 53% of patients requiring no supplemental treatment up to six months. We anticipate initial topline data from our Phase 2 trial in the second half of 2023."

The twelve-month, randomized, controlled Phase 2 DAVIO 2 trial of EYP-1901 for wet AMD is expected to enroll approximately 150 patients, previously treated with a standard-of-care anti-VEGF therapy, randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg) or an 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 DAVIO 2 trial is change in best corrected visual acuity (BCVA) compared to the aflibercept control six-months after the EYP-1901 injection. Secondary efficacy endpoints include change in central subfield thickness (CST) as measured by optical coherence tomography (OCT), time to first supplemental anti-VEGF, and safety. More information about the trial is available at clinicaltrials.gov (identifier: NCT05381948).

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment 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 DAVIO Phase 1 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% and 35% of eyes did not require supplemental anti-VEGF injections up to six and twelve months, respectively, following a single dose of EYP-1901. Phase 2 clinical trials are underway for wet AMD and planned in non-proliferative diabetic retinopathy in Q3 2022 and diabetic macular edema in 2023. 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 anti-VEGF 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 novel sustained delivery 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.

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