EyePoint Pharmaceuticals Presents Interim Masked Safety Data and Patient Baseline Characteristics for DAVIO 2 Clinical Trial at OIS Retina Innovation Summit

July 27, 2023

Interim safety data from the Phase 2 DAVIO 2 trial continues to demonstrate EYP-1901 is well tolerated with no reported drug-related ocular or systemic SAEs

Patient demographics demonstrate the Phase 2 DAVIO 2 population has a better baseline BCVA and decreased CST compared to the Phase 1 DAVIO trial cohort at trial start

Phase 2 DAVIO 2 clinical trial remains on track to report topline data in December 2023

WATERTOWN, Mass., July 27, 2023 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced interim masked safety data and baseline patient demographics from its Phase 2 DAVIO 2 clinical trial of EYP-1901, a potential sustained delivery maintenance treatment for wet age-related macular degeneration (wet AMD). These data are being presented today at the OIS Retina Innovation Summit in Seattle, WA by Nancy Lurker, Executive Vice-Chair of EyePoint Pharmaceuticals.

“EYP-1901 continues to demonstrate an excellent safety profile in the Phase 2 DAVIO 2 trial with no reported drug-related ocular serious adverse events (SAEs) and no reported drug-related systemic SAEs in the 160 enrolled patients as of July 1, 2023,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. “Safety is paramount for both patients and physicians in the development of ophthalmic treatments, and these data support EYP-1901’s continued track record of safety in humans. We are developing EYP-1901 as a sustained delivery therapeutic option to maintain vision in a majority of wet AMD patients for up to six-months or longer, while also reducing the treatment burden of frequent injections and improving treatment compliance. Additionally, we are also pleased to present the Phase 2 DAVIO 2 patient baseline characteristics, demonstrating DAVIO 2 patients had better starting visual acuity and less central subfield thickness (CST) than the Phase 1 DAVIO cohort. We look forward to sharing our topline results from the DAVIO 2 trial in December of this year.”

A masked safety summary as of July 1, 2023 found that there have been no reported drug-related ocular SAEs and no reported drug-related systemic SAEs in the DAVIO 2 trial. There were two ocular SAEs unrelated to EYP-1901 in the trial:

- Retinal detachment in a study eye detected at week 1 (one week post initial aflibercept injection, prior to EYP-1901 injection)
- Retinal hemorrhage in a non-study fellow eye

EyePoint also presented the Phase 2 DAVIO 2 trial screening characteristics and provided a comparison to baseline demographics of the Phase 1 DAVIO patients. Interim baseline data on patients in the Phase 2 DAVIO 2 trial as of July 1, 2023 reveal that patients feature a mean best corrected visual acuity (BCVA) of 74 letters, compared with a mean BCVA of 69 letters in the Phase 1 DAVIO trial. Mean CST in the Phase 2 DAVIO 2 trial was 265 µm, compared to 299 µm in the Phase 1 DAVIO trial. Mean age of patients in the Phase 2 DAVIO 2 trial is 76 years old, compared to 77.4 years old in the Phase 1 DAVIO trial.

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with previously treated wet AMD. All enrolled patients had been previously treated with standard-of-care anti-VEGF therapy and were 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 BCVA compared to the aflibercept control, six-months after the EYP-1901 injection. Secondary efficacy endpoints include change in CST as measured by optical coherence tomography (OCT), number of eyes that remain free of supplemental anti-VEGF injections, number of aflibercept injections in each group, 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 for retinal disease combining a bioerodible formulation of EyePoint's proprietary Durasert® delivery technology (Durasert E™) with vorolanib, a tyrosine kinase inhibitor. Positive safety and efficacy data from the Phase 1 DAVIO clinical trial of EYP-1901 in wet AMD showed a positive safety profile with stable visual acuity and OCT. Further, the data demonstrated an impressive treatment burden reduction of 75% at six months and 73% at the 12-month visit following a single dose of EYP-1901. Phase 2 trials are fully enrolled in wet AMD and non-proliferative diabetic retinopathy, and a diabetic macular edema trial is planned for initiation in Q1 2024. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a 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 bioerodible Durasert E™ technology for sustained intraocular drug delivery including EYP-1901, an investigational sustained delivery intravitreal anti-VEGF treatment currently in Phase 2 clinical trials. The proven Durasert® drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. For more information visit www.eyepointpharma.com.

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Source: EyePoint Pharmaceuticals, Inc.