



**EYEPOINT**<sup>®</sup>  
PHARMACEUTICALS

# EYP-1901 - DAVIO Phase 1 Clinical Trial Data Backgrounder

## About EYP-1901

- EYP-1901 is an anti-vascular endothelial growth factor (anti-VEGF) therapy being investigated to treat wet age-related macular degeneration (wet AMD).
- This innovative office-based, intravitreal treatment leverages EyePoint's proprietary Durasert<sup>®</sup> technology for sustained intraocular drug delivery to deliver vorolanib, a tyrosine kinase inhibitor (TKI), for an extended duration, as opposed to the current standard of care treatment requiring injections every month or two.
  - Durasert<sup>®</sup> technology is currently used as a delivery system for four U.S. Food and Drug Administration (FDA) approved treatments.
- With EYP-1901, the sustained, stable release over months may lead to fewer patient visits, fewer injections, and possibly better visual outcomes through uninterrupted receptor blockade. In addition, EYP-1901 has the potential for up to every six-month dosing, which would address treatment adherence issues and, therefore, possibly treat wet AMD more effectively.
- Wet AMD is a serious eye disorder that can cause progressive central vision loss due to fluid leakage and hemorrhage into the macula. If untreated or undertreated, legal blindness can occur.



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# About the Phase 1 Durasert and Vorolanib in Ophthalmology (DAVIO) Clinical Trial

## Trial Design

The DAVIO trial is a Phase 1 open-label, dose escalation clinical trial of EYP-1901 that enrolled 17 patients all of whom had previously treated wet AMD. One injection of EYP-1901 was given at day 0 of the study. No retreatments occurred in this trial.

### DAVIO trial endpoints:

- Primary Endpoint:
  - Safety
- Key Secondary Endpoints:
  - Best-corrected visual acuity (BCVA)
  - Central subfield thickness (CST) as measured by optical coherence tomography (OCT)

### Other potential efficacy data of interest:

- Number of eyes that remain “rescue- or treatment-free” at various time points
- Reduction in the anti-VEGF “treatment burden” following administration of EYP-1901. “Treatment burden” refers to the reduction in standard-of-care anti-VEGF injections after the injection of EYP-1901 as compared to prior to treatment

### Four defined dosing cohorts:

1. Low Dose (440 ug, single dose)
2. Low Medium Dose (1030 ug, single dose)
3. Mid Dose (2060 ug, single dose)
4. High Dose (3090 ug, single dose)

### Key inclusion criteria:

- Subjects diagnosed with wet AMD in the study eye
- Subjects must have received at least three prior injections with an anti-VEGF product (bevacizumab, ranibizumab, or aflibercept) in the six months prior to the Screening Visit, in the study eye
- Demonstrated response to the intravitreal anti-VEGF treatment in the study eye. BCVA using ETDRS charts must be between 25 letters (20/320 Snellen equivalent) and 75 letters (20/32 Snellen equivalent)



## DAVIO Trial Results To-Date

At the American Academy of Ophthalmology (AAO) 2021 Annual Meeting, EyePoint Reported Positive Interim Safety and Efficacy Data from the Phase 1 DAVIO Clinical Trial Evaluating EYP-1901 for the Treatment of Wet AMD.

- Interim six-month results show positive safety data, no dose limiting toxicities, no ocular serious adverse events (SAEs), and no drug-related systemic SAEs
- Stable BCVA and CST were achieved
- 76% and 53% of patients were rescue-free up to four and six months, respectively, following a single injection of EYP-1901
- Overall treatment burden reduced by 79% at six months
- Phase 2 clinical trials expected to initiate in 2022

Visit the [EyePoint Newsroom](#) to learn more.

## About Wet AMD

- Wet AMD is one of two types of AMD. The other type is dry age-related macular degeneration (dry AMD).
  - Approximately 11 million Americans are impacted by AMD.
  - Wet AMD accounts for up to 15 percent of all AMD cases but is responsible for 90 percent of legal blindness.
- Wet AMD is the onset of abnormal blood vessels under the center of the retina (macula) located in the back of the eye. The new blood vessels leak fluid and/or blood causing the loss of vision and, if untreated, permanent scarring in the central retina.
- Wet AMD is the leading cause of vision loss among people 50 years of age and older in the U.S.
- A key symptom of wet AMD is sudden, painless central vision loss. Other symptoms include distortion or a blind spot in the central vision. The blind spot can appear gray, red, or black. Straight lines may look wavy because the macula is no longer smooth. Side or “peripheral” vision is rarely affected.

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### EyePoint Pharmaceuticals’ Commitment to Patients with Serious Eye Disorders

- EyePoint Pharmaceuticals is committed to developing innovative treatment options to improve the lives of people with serious eye disorders.
- The Company has a compelling pipeline focused on retinal disease that leverages its proprietary Durasert® technology for sustained intraocular drug delivery that allows for more time in between treatment administration.
- EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. To learn more about the Company, please visit <https://eyepointpharma.com/> and connect on [Twitter](#), [LinkedIn](#) and [Facebook](#).

