

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 18, 2022

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-51122
(Commission File Number)

26-2774444
(IRS Employer
Identification No.)

480 Pleasant Street
Watertown, Massachusetts
(Address of Principal Executive Offices)

02472
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 926-5000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	EYPT	The NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On July 18, 2022, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing its preliminary second quarter net product revenue, cash and investments on hand, and certain other corporate updates. The amounts included in the press release were calculated prior to the completion of a review by the Company's independent registered public accounting firm and are therefore subject to change upon completion of the Company's quarterly report for the period ended June 30, 2022. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of June 30, 2022. A copy of the press release is filed as Exhibit 99.1 hereto.

The information included under Item 2.02 of this current report on Form 8-K, including Exhibit 99.1, is deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and, therefore, may be incorporated by reference in filings under the Securities Act of 1933, as amended.

Item 8.01 Other Events.

On the same date, EyePoint Pharmaceuticals, Inc. posted the Company's Investor Day 2022 presentation on its website at www.eyepointpharma.com. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release by EyePoint Pharmaceuticals, Inc. dated July 18, 2022
99.2	Investor Day 2022 Presentation of EyePoint Pharmaceuticals, Inc. dated July 18, 2022
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EYEPOINT PHARMACEUTICALS, INC.

Date: July 18, 2022

By: /s/ George O. Elston
George O. Elston
Chief Financial Officer

EyePoint Pharmaceuticals Investor Day to Highlight EYP-1901 and Durasert® Technology Developments and Provide a Financial Update

- *Positive 12-Month Safety and Efficacy Data from Phase 1 DAVIO Clinical Trial Evaluating EYP-1901 for the Treatment of Wet AMD announced at ASRS 2022 Annual Meeting*

- *Phase 2 clinical trial (DAVIO 2) in wet AMD and in non-proliferative diabetic retinopathy (NPDR) patient dosing anticipated in Q3 2022*

- *Net product revenue of \$11.3 million in Q2 2022; a 30% increase from Q2 2021*

- *\$171 million of cash and investments at June 30, 2022*

- *CMS Draft Hospital Outpatient Rule does not extend pass-through status of expiring drugs which will impact reimbursement for DEXYCU after December 31, 2022*

- *Investor Day live webcast today, July 18, 2022 at 8 a.m. ET*

WATERTOWN, Mass., July 18, 2022 (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 the Company will highlight historical and ongoing developments for its lead pipeline program, EYP-1901 and its Durasert platform technology, and will also provide a financial update during its Investor Day today, Monday July 18, 2022, from 8:00 a.m. to 11 a.m. ET.

“EyePoint is helping to change the treatment paradigm of wet AMD using a ‘treat to maintain’ maintenance therapy approach with EYP-1901, an investigational sustained delivery anti-VEGF treatment,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. “We are excited to share updated pre-clinical and human data for EYP-1901 during our Investor Day, along with the 12-month DAVIO Phase 1 clinical trial data, which we just released last week at the American Society of Retinal Surgeons (ASRS) Annual Meeting.”

Investor Day will feature commentary from EyePoint’s management team as well as key opinion leader guest speakers, Carl D. Regillo, M.D., FACS, Professor of Ophthalmology, Thomas Jefferson University and Charles C. Wykoff, M.D., Ph.D., Director of Research, Retina Consultants of Texas.

Investor Day Highlights:

- Nancy Lurker, Chief Executive Officer will present an overview of the Company.
 - Jay Duker M.D., Chief Operating Officer will present an overview of EYP-1901 using a bioerodible formulation of EyePoint’s proprietary Durasert® technology for sustained intraocular drug delivery, which has been safely administered to over 80,000 patients’ eyes across four U.S. FDA approved products.
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- Said Saim, Ph.D., Chief Technology Officer, will present an overview of EYP-1901 preclinical data, including its development and formulation and new pre-clinical data highlighting neuroprotection potential for EYP-1901.
- Carl Regillo, M.D., FACS, Professor of Ophthalmology, Thomas Jefferson University, will present the 12-month safety and efficacy data from the Phase 1 DAVIO clinical trial evaluating EYP-1901 for the potential treatment of wet AMD that showed continued positive safety and efficacy for EYP-1901 including no serious ocular adverse events and 35% of patients out to 12 months with no supplemental anti-VEGF treatment after the initial EYP-1901 insert was administered.
- Charles Wykoff, M.D., Ph.D., Director of Research, Retina Consultants of Texas, and Jay Duker M.D., Chief Operating Officer, will discuss the potential opportunity of EYP-1901 as a “treat to maintain” maintenance therapy for wet AMD.
- Dario Paggiarino, M.D., Chief Medical Officer will present the EYP-1901 Phase 2 plans in wet AMD and NPDR with first patient dosing anticipated in Q3 2022. He will also provide an update on two ongoing Phase 4 studies for YUTIQ®, (fluocinolone acetonide intravitreal implant) 0.18 mg, for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye.
- George Elston, Chief Financial Officer, will provide a financial update on Q2 2022 performance with net product revenue of \$11.3 million for the quarter and cash and investments of \$171 million at June 30, 2022. He will also discuss the potential impact of the 2023 CMS Draft HOPPS (Hospital Outpatient) rule released last week in which CMS has indicated its intention not to provide further pass-through extension to expiring products, including DEXYCU. If the draft rule becomes final, DEXYCU will lose pass-through separate reimbursement status on December 31, 2022 and will instead be bundled into the general Cataract procedure reimbursement code starting on January 1, 2023.

The preliminary second quarter 2022 revenue results and cash and investments on hand included in this release were calculated prior to the completion of a review by the Company’s independent registered public accounting firm and are therefore subject to adjustment.

Investor Day Webcast Information

A webcast and subsequent archived replay of the presentation may be accessed via the Investors section of the Company website at www.eyepointpharma.com. The replay will be available for 90 days after the event.

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. Phase 2 clinical trials for wet AMD (DAVIO 2) and non-proliferative diabetic retinopathy are expected to begin dosing patients in Q3 2022. A Phase 2 clinical trial is planned for diabetic macular edema in 2023. 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 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.

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EYEPOINT PHARMACEUTICALS
INVESTOR
DAY 2022

UNIVERSITY CLUB | NEW YORK CITY | JULY 18, 2022



Forward-Looking Statements

Various statements made in this presentation are forward-looking, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our expectations regarding the potential benefits of our partnerships and strategic alliances with other companies, as well as the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a sustained delivery treatment for wet age-related macular degeneration and non-proliferative diabetic retinopathy; and our longer term financial and business goals and expectations, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the extent to which COVID-19 impacts our business; 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®; the success of current and future license agreements, including our agreements with Ocumension Therapeutics, Equinox Science and Betta Pharmaceuticals; termination or breach of current 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 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 our 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.

INTRODUCTIONS AND AGENDA

Nancy Lurker | President and Chief Executive Officer

Investor Day: Speakers - Management



Nancy Lurker

CEO

3x CEO with 30 years biopharmaceutical experience across multiple therapeutic areas; she has a proven record of generating revenue growth and facilitating strategic partnerships



Jay Duker, MD

COO

30 years managing retinal diseases and is a 12-time clinical trial investigator/co investigator; he has started 3 companies, ~345 ophthalmic publications, and extensive drug delivery, target identification and validation knowledge



George O. Elston

CFO

20 years of C-Level experience with strong and established relationships across wall street, buy-side, venture capital and pharma/biotech resulting in transformative company-building and M&A transactions covering a wide range of financing and partnering

Investor Day: Speakers - Management



Dario Paggiarino, MD

CMO

>20 years of ophthalmic small molecule, biologic, and device clinical development and medical affairs; has led >100 Phase I - IV development programs leading to several FDA and ex- US approvals



Said Saim, Ph.D.

CTO

>25 years of pre-formulation, formulation, process development and tech transfer experience resulting in several FDA approvals and >20 patents and 20 publications

Investor Day: KOL Guest Speakers



Carl D. Regillo

MD, FACS

Professor of Ophthalmology, Thomas Jefferson University Chief of the Retina Service, Wills Eye Hospital Founder, Wills Eye Clinical Retina Research Unit in Philadelphia



Charles C. Wykoff

MD, Ph.D.

Director of Research, Retina Consultants of Texas, Chairman of the Research and Clinical Trials Committee, Retina Consultants of America, Deputy Chair of Ophthalmology, Blanton Eye Institute at Houston Methodist Hospital

Investor Day: Agenda

PRESENTATION SPEAKER

Introductions

Nancy Lurker

EyePoint Overview

Nancy Lurker

Durasert® and EYP-1901 Overview

Jay Duker, M.D.

EYP-1901: Development and Formulation

Said Saim, Ph.D.

EYP-1901: DAVIO 12-Month Data

Carl Regillo, M.D.

EYP-1901: Treat to Maintain

Jay Duker, M.D.
Charlie Wykoff, M.D.

Investor Day: Agenda

PRESENTATION SPEAKER

EYP-1901: Phase 2 Plans

Dario Paggiarino, M.D.

YUTIQ Clinical Update

Dario Paggiarino, M.D.

Financial Update

George Elston

Q&A

All

Closing Remarks

Nancy Lurker

COMPANY OVERVIEW

Nancy Lurker | President and Chief Executive Officer

COMPANY OVERVIEW

Compelling Pipeline Leverages Proven Durasert[®] Technology

EYP-1901 is key pipeline program

- Vorolanib, a TKI in bioerodible Durasert
- Positive safety and efficacy data from Phase 1 DAVIO clinical trial
- Phase 2 clinical trials in wet AMD and in non-proliferative diabetic retinopathy (NPDR) expected to begin in Q3 2022

Durasert[®] - proven intravitreal (IVT) drug delivery

- Sustained ocular drug delivery
- Constant (zero-order kinetics) stable release of drug
- Safely administered to over 80,000 patient eyes across four FDA approved products

Strong balance sheet with growing revenue

- \$171 million in cash and investments on June 30, 2022
- Cash runway into 2H 2024
- Commercial franchise positioned for 2022 break-even

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PLATFORM TECHNOLOGY
DURASERT®

Jay Duker, M.D. | Chief Operating Officer

TECHNOLOGY

DURASERT®



Safe Sustained Intravitreal Drug Delivery

Used in four of six FDA approved intravitreal sustained delivery products

Delivered by a single in-office intravitreal injection

Continuous, stable release of drug

Non-Erodible Products

- YUTIQ® (EyePoint)
- ILUVIEN® (Alimera)
- RETISERT® (B&L)
- VITRASERT® (B&L)

Bioerodible: EYP-1901

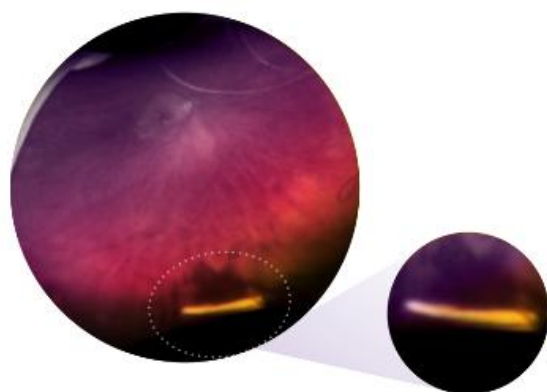
- Polyimide coating eliminated
- Initial drug burst from insert surface
- Constant, zero-order kinetic release over months

EYP-1901

OVERVIEW

Jay Duker, M.D. | Chief Operating Officer

EYP-1901: Vorolanib in Bioerodible Durasert[®]



EYP-1901 insert at month 5 post-injection

EYP-1901

- Single IVT injection of up to 3 inserts
- Bioerodible formulation of Durasert
- Initial drug burst from surface of insert to rapidly reach therapeutic levels in ocular tissues
- Zero order kinetics release

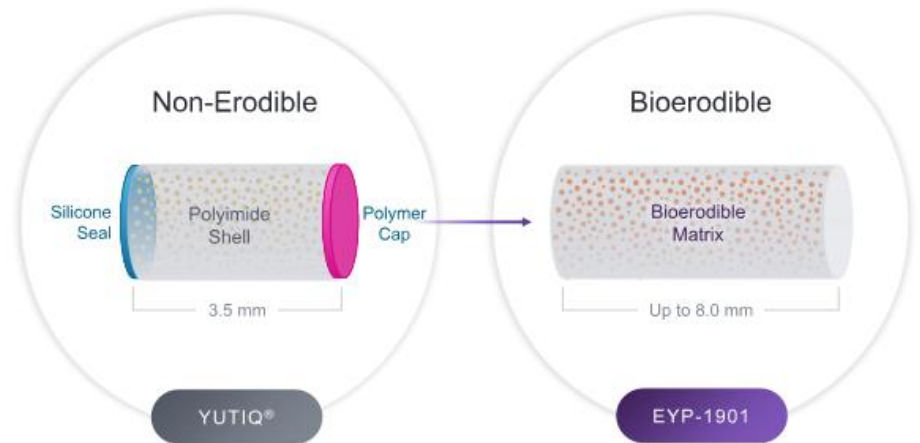
Vorolanib

- Receptor-binding tyrosine kinase inhibitor (TKI)
- Binds receptors of all VEGF growth factors
- Oral formulation studied in Phase 1 and Phase 2 wet AMD clinical trials^{1,2}

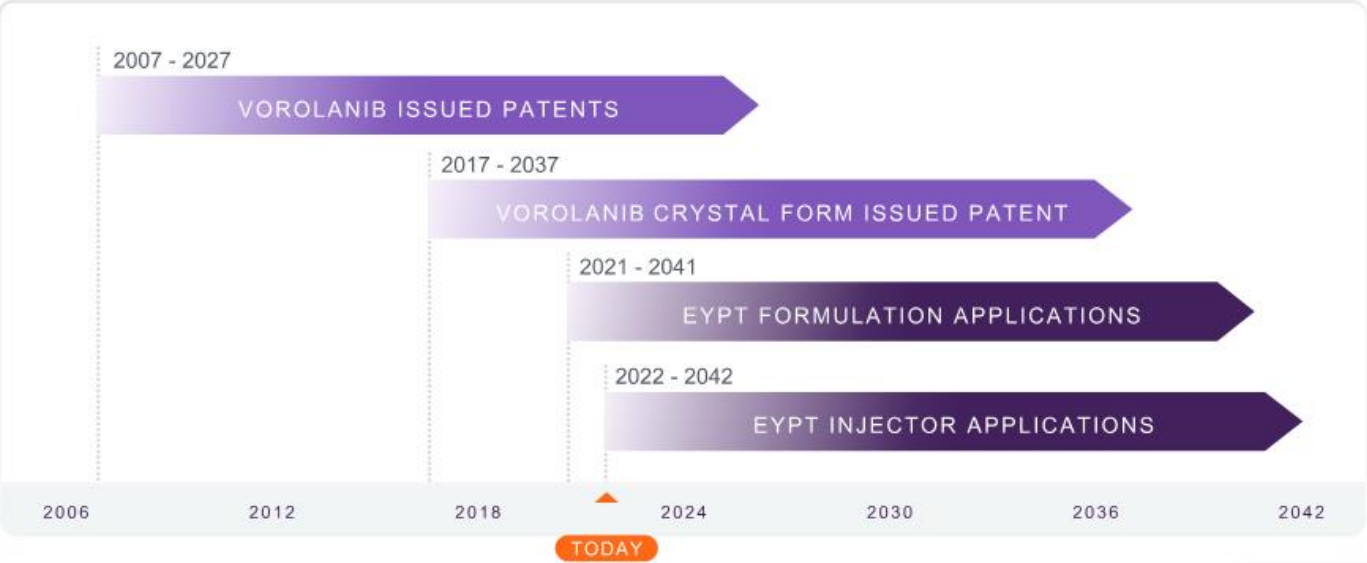
1. Jackson et al. JAMA Ophthalmol 2017. 2. Cohen MN et al. Br J Ophthalmol. 2021.

EYP-1901 utilizes a bioerodible formulation of Durasert for repeated IVT injections

- Sustained, zero-order kinetics drug release over 6-9 months in bioerodible
- High drug load per insert
- Insert is ~1/5,000 the volume of the vitreous



EYP-1901, vorolanib and new injector hold strong patents and patent applications for long term value



EYP-1901

VOROLANIB OVERVIEW

Said Saim, Ph.D. | Chief Technology Officer

WHY VOROLANIB?

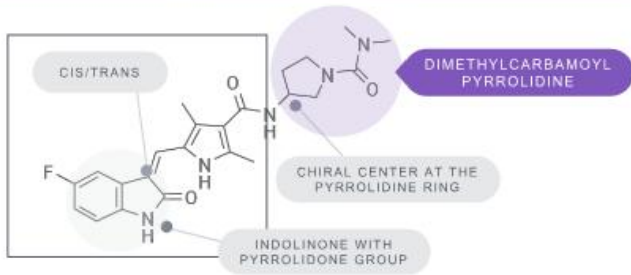
Vorolanib is a specifically designed TKI for reduced off-target binding

Vorolanib selected after evaluation of over 100 small molecule TKIs

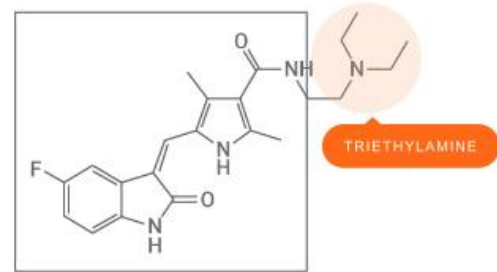
- Previously studied in Phase 1 and Phase 2 clinical trials as an oral therapy with compelling efficacy data and no ocular toxicity
- Intracellular binding of all VEGF receptors thereby blocking receptors of all VEGF family of growth factors with strong affinity to VEGF receptor 2
- Reduced off-target binding of receptors associated with TKI systemic side effects

Vorolanib was specifically designed to reduce off target binding that may lead to an improved safety profile

vorolanib

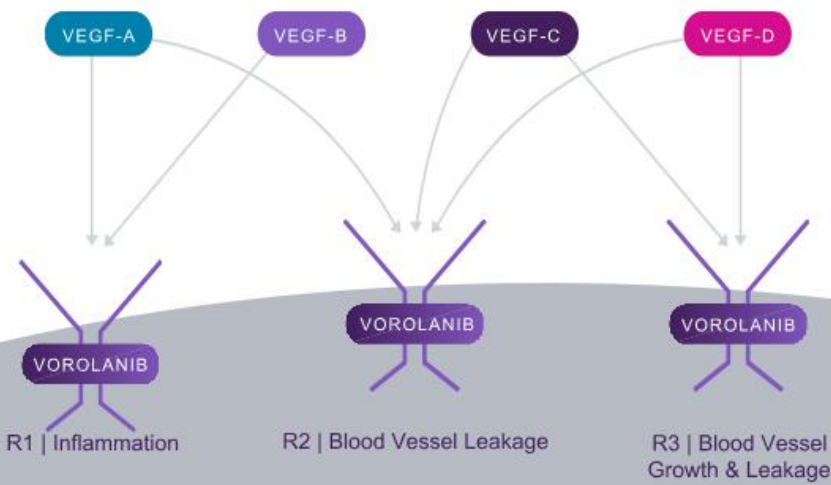


sunitinib



Vorolanib binds receptors of all VEGF growth factors with strong affinity to VEGF receptor 2 - a receptor associated with blood vessel leakage

VEGF SIGNALING PATHWAYS



VOROLANIB INHIBITS VEGFR

- Binds to the intracellular domain of tyrosine kinases
- Targets the angiogenic VEGF receptors R1, R2 and R3 with high potency

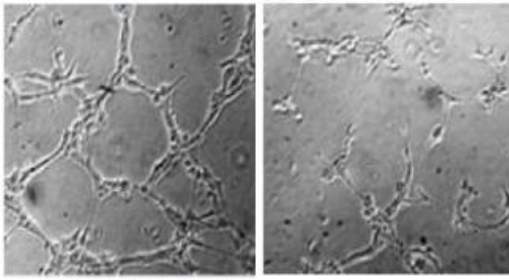
EYP-1901

VOROLANIB PRE-CLINICAL POC PHARMACOLOGY STUDIES

Said Saim, Ph.D. | Chief Technology Officer

Vorolanib significantly reduces new blood vessel formation in an established cell model

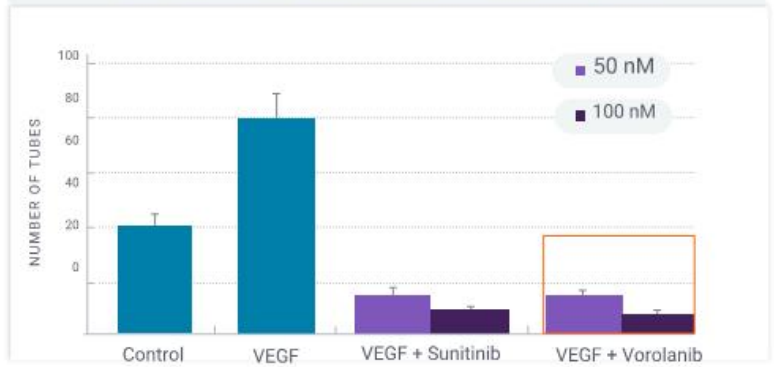
Tube formation in cultured HUVEC cells



VEGF

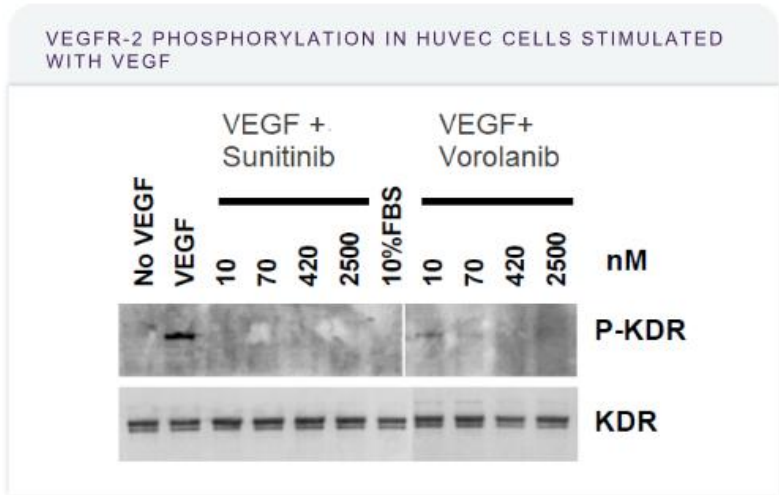
VEGF + VOROLANIB (50nM)

Effect on HUVEC tube formation induced by VEGF



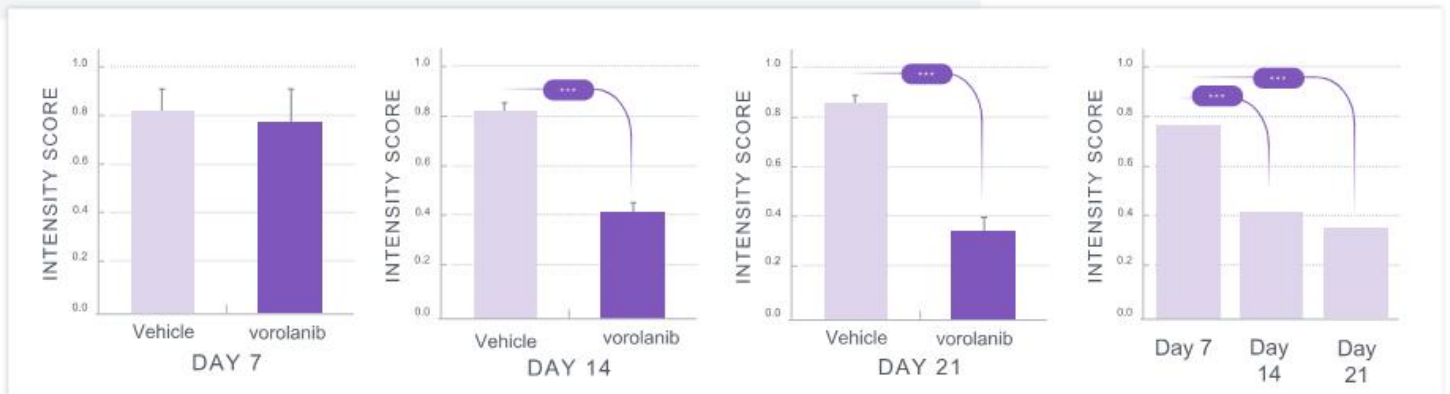
Vorolanib inhibited blood vessel tube formation at very low concentrations of 50 to 100 nM (IC50 is 52 nM; equivalent to 0.052 μ M or 22.9 ng/g) in a dose dependent manner

Vorolanib concentrations at only 20% of IC50 induced significant inhibition of VEGFR phosphorylation



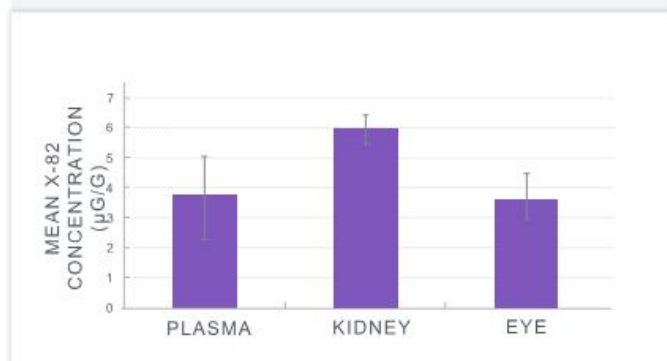
In a validated laser CNV animal study vorolanib demonstrated significantly lower vascular leakage suggesting activity in wet AMD

TREATMENT STARTED AT DAY 7 AFTER LASER INJURY | 30 MG/KG/D



Vorolanib demonstrated inhibition of retinal neovascularization in an animal study suggesting activity in diabetic retinopathy

LEVELS IN EYE SIMILAR TO LEVELS IN PLASMA

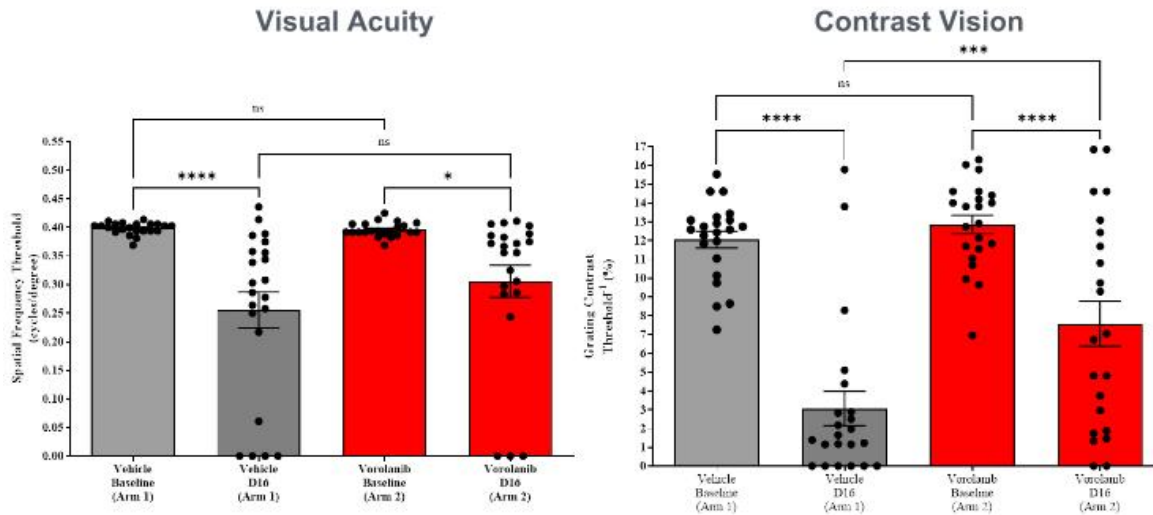


HIGH EFFICACY (~71% REDUCTION IN NV AREA)



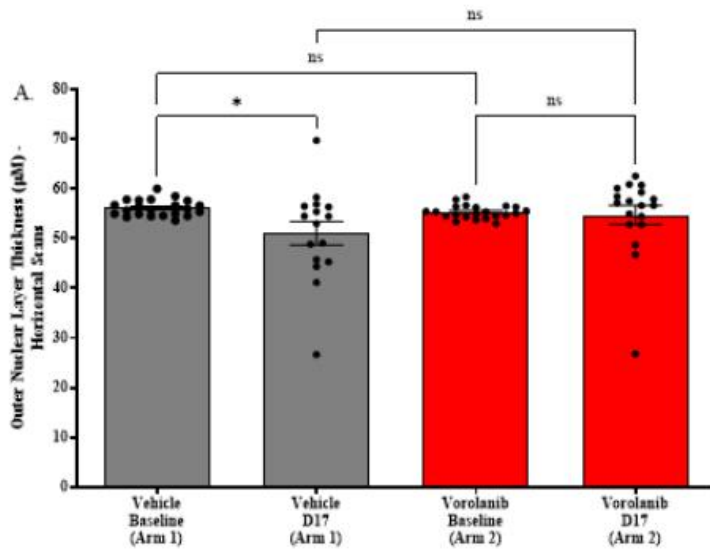
Hu Huang, Effects of X-82 on retinal neovascularization (NV) in a murine model of oxygen-induced retinopathy (OIR) (X-82-NCL-033) : 40 mg/kg/d in solution/IP injection; 75% O2 from day 1 to Day 12; Room air from Day 12-17; X-82 at Day 12.

Optokinetic tracking in validated retinal detachment mouse model suggests that vorolanib has neuroprotective properties



- Higher visual acuity function in vorolanib treated mice vs vehicle
- Significantly higher contrast vision in vorolanib treated mice vs vehicle

OCT in validated retinal detachment mouse model further suggests that vorolanib has neuroprotective properties



Preservation of Structure: Significant loss of ONL thickness in vehicle eyes but not in vorolanib eyes suggesting that vorolanib protects photoreceptors

VOROLANIB

Summary and Key Takeaways

- Binds intracellular domain of receptors
- Compelling efficacy data as an oral therapy in Phase 1 and 2 clinical trials
- Levels as low as 20% of IC50 show significant inhibition of VEGFR2 phosphorylation
- Retinal detachment model indicates potential neuroprotection by vorolanib

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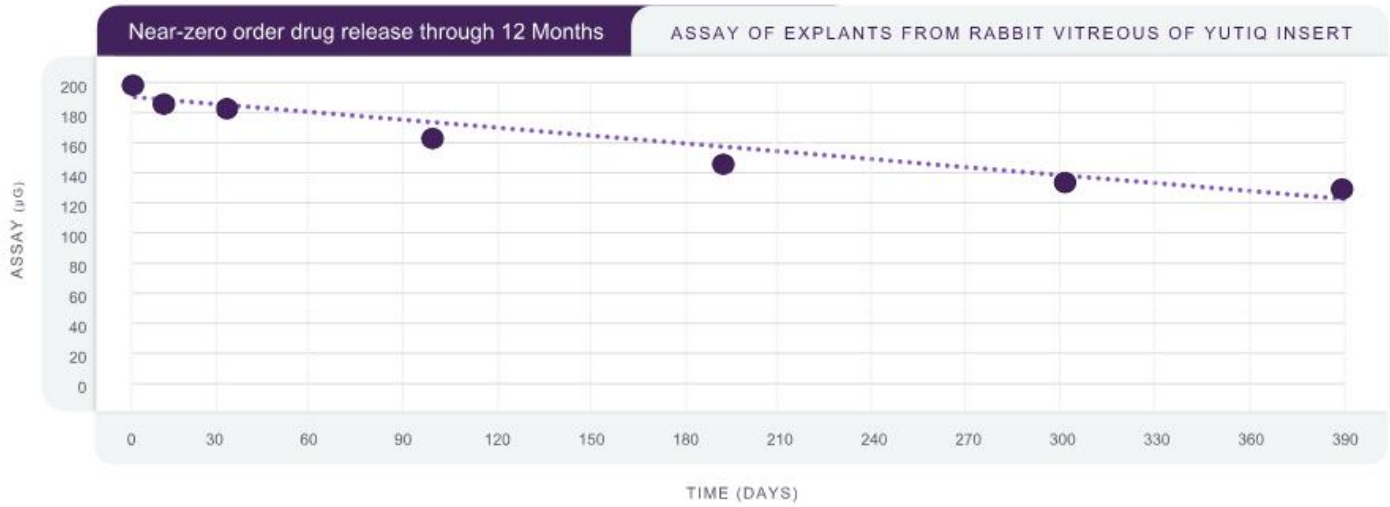
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EYP-1901

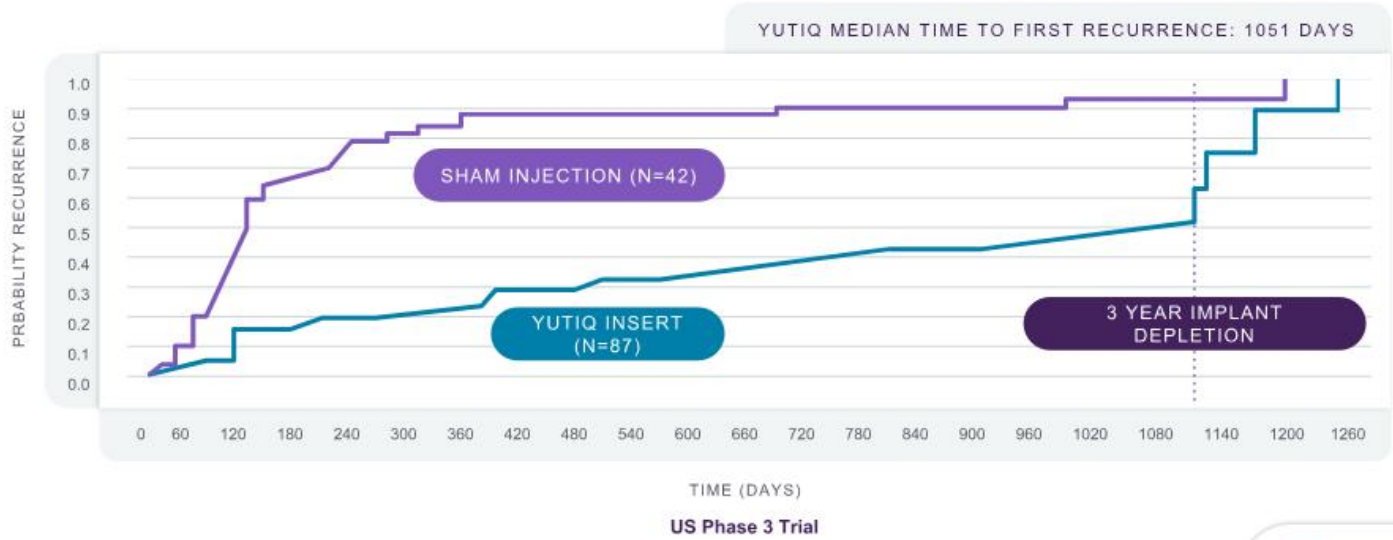
PRECLINICAL PK DATA

Said Saim, Ph.D. | Chief Technology Officer

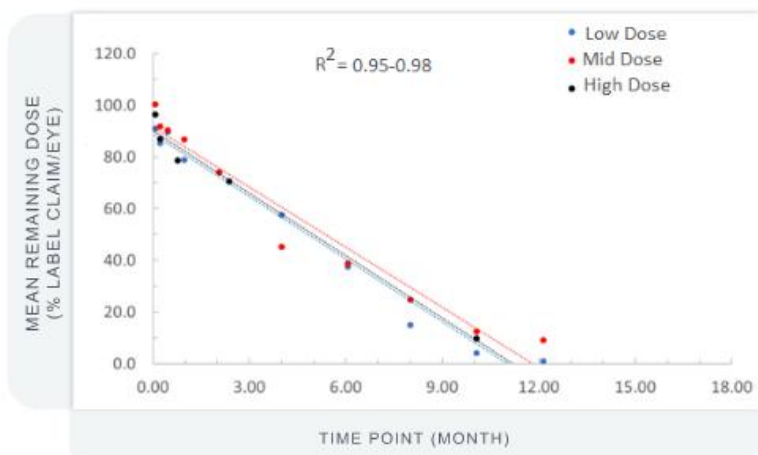
YUTIQ provides a benchmark for zero-order kinetics release over 12 months in non-erodible Durasert



YUTIQ demonstrates continuous 3-year delivery and efficacy in non-erodible Durasert

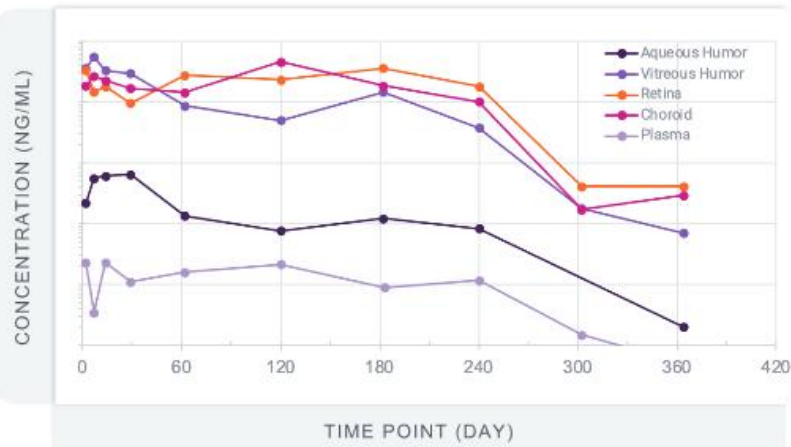


EYP-1901 reflects near zero-order drug release across multiple doses in a rabbit model



- Near zero-order drug release is observed over 8-10 months
- Inserts are essentially depleted past 8 months, confirming observed pharmacokinetics in ocular tissues
- Release rate is dose proportional
- Consistent release of micrograms levels of drug per day

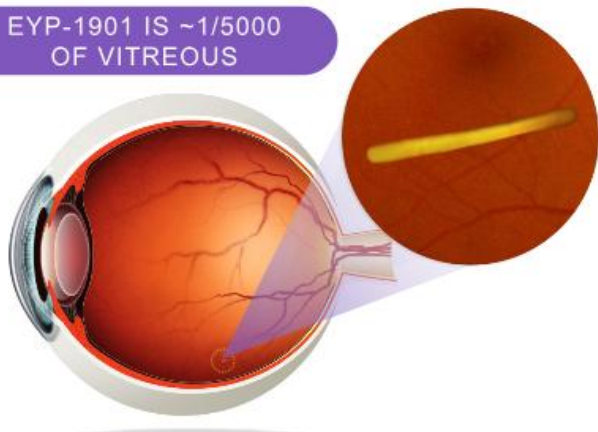
Pharmacokinetic profile of EYP-1901 in local tissues supports zero-order kinetics release and sustained receptor binding above IC50 in a rabbit model



- Initial burst followed by steady state levels of vorolanib in all ocular tissues
- Levels approximately an order of magnitude higher than IC50 observed at steady state in retina and choroids
- Low levels in plasma and aqueous humor

EYP-1901 bioerodible formulation supported by in-vitro dissolution model

EYP-1901 IS ~1/5000
OF VITREOUS



INSERT AT 12 MONTHS AND DAY 0



Enlarged for illustrative purposes

EYP-1901 PRECLINICAL PK
AND SAFETY DATA

Summary and Key Takeaways

- Consistent, zero order release of $\mu\text{g}/\text{day}$ through 9 months
- Steady state levels in ocular tissues for 8-9 months at levels higher than IC50 for VEGFR2 inhibition
- Release is dose proportional
- Inserts are bioeroded over time

EYP-1901

VOROLANIB ORAL FORMULATION CLINICAL TRIALS

Jay Duker, M.D. | Chief Operating Officer

Oral vorolanib phase 1 clinical trial results

Demonstrated clinical
activity in wet AMD in
oral formulation

Trial Design

- Open label, 24 weeks, dose escalation, no control, oral delivery
- N=25

Phase 1: Results

- BCVA maintained to within 4 letters of baseline or improved in all but 1 participant
- 60% (15/25) of patients required no supplemental anti-VEGF injection while on oral vorolanib
- Excluding the low dose, 72% of patients required no supplemental anti-VEGF injection
- Mean OCT thickness was reduced by $-50 \pm 97 \mu\text{m}$
- Mean OCT thickness in treatment-naïve patients was reduced by $\sim 80 \mu\text{m}$

BCVA: best corrected visual acuity OCT: ocular coherence tomography.
Study performed by Tyrogenix.

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Vorolanib Phase 2 Clinical Trial Results

Reduced supplemental therapy versus anti-VEGF PRN for all doses with no ocular toxicity

For subjects followed ≥ 6 months	Placebo n=33	50 mg n=34	100 mg n=30	200 mg n=26
Median number of anti-VEGF injections*	9.0	6.1	5.8	4.6
Percent of Patients w/ no supplemental anti-VEGF therapy	2.6	7.5	10.3	20.5

Strict pre-defined supplement criteria with anti-VEGF therapy:

- Any increase in fluid on OCT compared to screening visit (~14 days after an IVT injection)
- New or increased macular hemorrhage by fundus photography

* Normalized for number of months on study. Study performed by Tyrogenix.

Oral vorolanib clinical trials showed well controlled fellow eye conversion to wet AMD

Phase 1 trial:

- **No** participant among the 25 completers developed new neovascular AMD in the fellow eye*

Phase 2 trial:

- Placebo group (PRN intravitreal Anti-VEGF)
 - ☒ **12.5%** - (3/24) of subjects with unilateral disease at baseline developed exudative AMD in their fellow eyes by 52 weeks
- Treated group (vorolanib at 50mg, 100mg, 200mg daily)
 - ☒ **1.3%** - (1/26), (0/27) and (0/23) in the 50 mg, 100 mg, and 200 mg, respectively developed exudative AMD in their fellow eye by 52 weeks

* One participant (receiving 50 mg daily) developed new exudation from a previously treated fellow eye CNV

* Study performed by Tyrogenix.

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EYP-1901

PHASE 1 DAVIO CLINICAL TRIAL 12 MONTH RESULTS

Carl Regillo, M.D.

EYP-1901 Phase 1 DAVIO Clinical Trial – “Durasert® and Vorolanib In Ophthalmology”

PROTOCOL SUMMARY

Enrollment

- Previously treated wet AMD eyes
- No exclusion for presence of fluid

Criteria for Supplemental Anti-VEGF Therapy*

- New fluid > 75 microns on OCT
- Loss of ≥ 2 lines of BCVA secondary to wet AMD
- New macular hemorrhage secondary to wet AMD

Methodology

- All patients received SoC anti-VEGF at screening
- All patients received a single dose of EYP-1901 at baseline (Day 0) ranging from 440 (μg) to 3090 (μg)
- No EYP-1901 redosing for duration of the study
- Clinical assessments and evaluation for supplemental anti-VEGF therapy every 4 weeks through month 12

Phase 1 Trial: A 12-month, multicenter, open-label, dose escalation, no control arm study of EYP-1901 in subjects with Wet AMD

EYP-1901 Phase 1 DAVIO clinical trial enrolled 17 patients over four different dosages

Primary Endpoint: Safety

- Ocular and non-ocular TEAEs through month-12

Secondary Endpoints

- Supplemental anti-VEGF therapy through 6-months
- Change in BCVA from baseline
- CST as measured by OCT



EYP-1901 Phase 1 DAVIO clinical trial participant overview

BASELINE CHARACTERISTICS

Mean age, range (years)	77.4
Female (n)	13/17
Mean BCVA, range (ETDRS letters)	69 letters
Mean CST, range (microns)	299 microns
Median length of time for Wet AMD Diagnosis	17
Mean # of anti-VEGF injections per year prior to enrollment	8.0 injections/year

BCVA: best corrected visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; CST: central subfield thickness

EYP-1901 Phase 1 DAVIO clinical trial demonstrated favorable overall safety data at 12-months meeting primary endpoint

Ocular AEs of particular interest:

- No vitreous floaters
- No endophthalmitis
- No retinal detachment
- No implant migration in the anterior chamber
- No retinal vasculitis
- No posterior segment inflammation

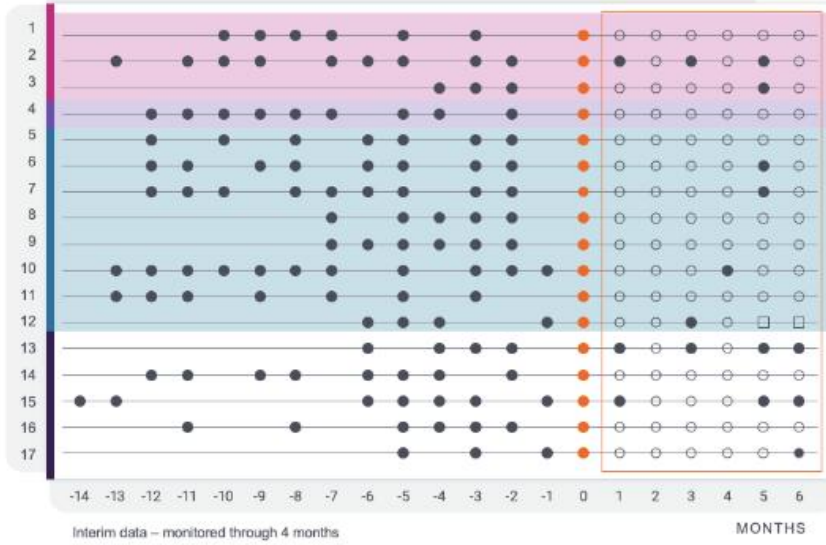
Ocular AEs observed:

- One eye: mild asymptomatic anterior chamber cell/flare;
 ☒ treated with Maxitrol® eyedrops – resolved in 8 days – no sequelae or recurrence
- One eye: asymptomatic vitreous hemorrhage from injection; observed

- No ocular serious adverse events (SAEs)
- No drug-related systemic SAEs
- No evidence of vorolanib-related ocular or systemic toxicity
- No Durasert-related toxicity or tolerance issues
- No dose limiting toxicity

EYP-1901 phase 1 DAVIO clinical trial demonstrated clinically significant reduction in treatment burden of 79% at 6-months

SOC ANTI-VEGF INJECTIONS BEFORE AND AFTER TREATMENT

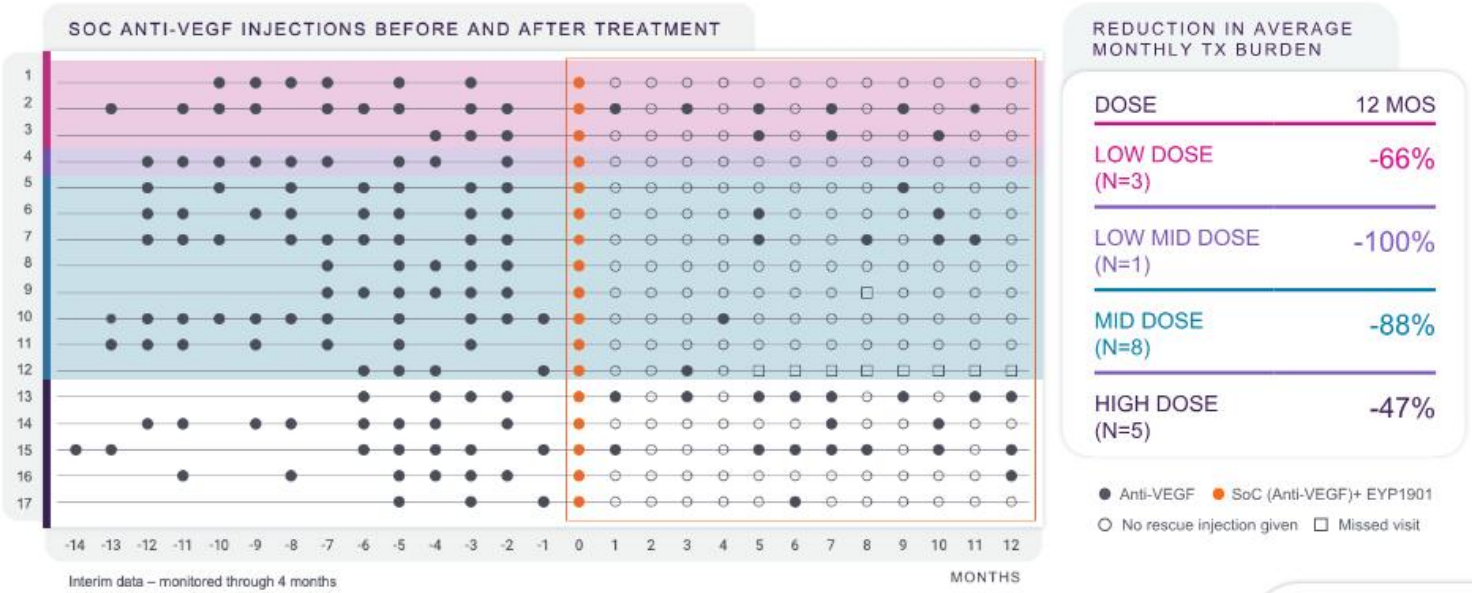


REDUCTION IN AVERAGE MONTHLY TX BURDEN

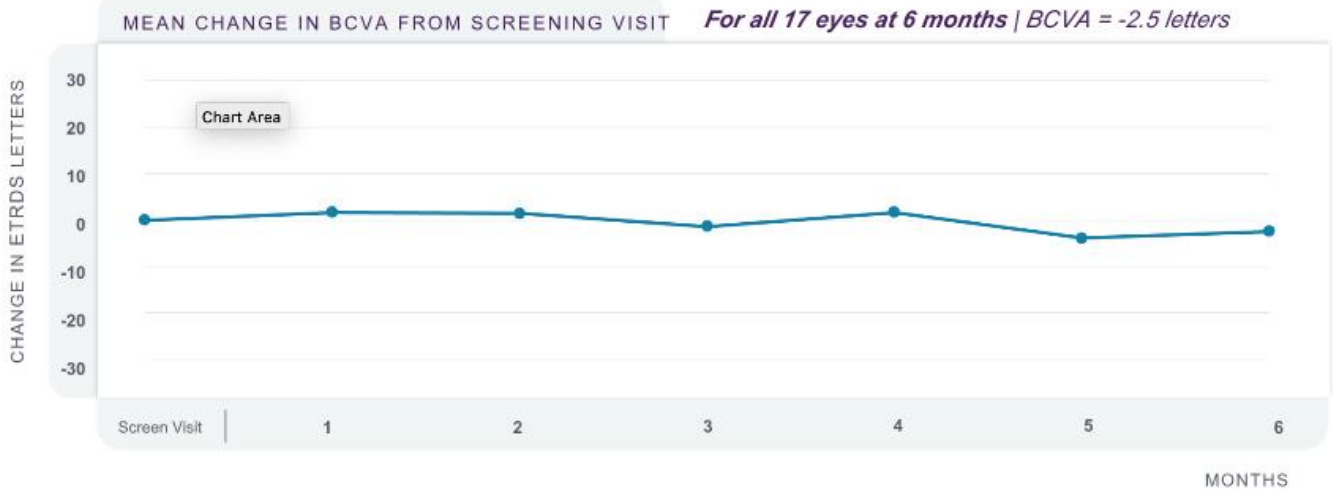
DOSE	%
LOW DOSE (N=3)	-70%
LOW MID DOSE (N=3)	-100%
MID DOSE (N=3)	-89%
HIGH DOSE (N=5)	-55%

- Anti-VEGF ● SoC (Anti-VEGF)+ EYP1901
- No rescue injection given □ Missed visit

EYP-1901 Phase 1 DAVIO clinical trial continues clinically significant reduction in treatment burden of 74% at 12-months



EYP-1901 Phase 1 DAVIO clinical trial results at 6-months: mean BCVA is stable after single treatment



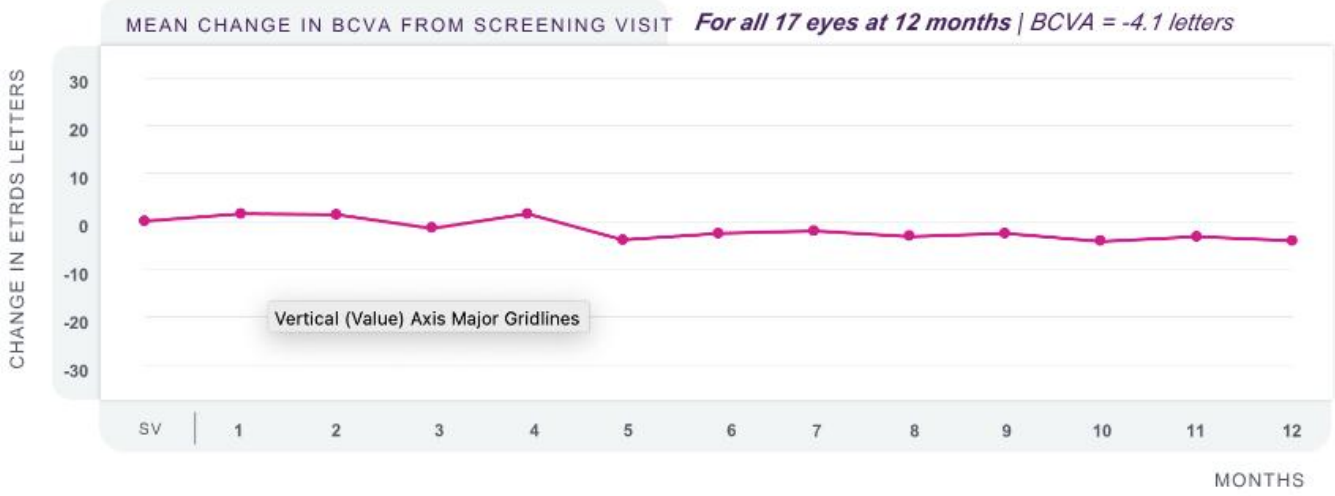
BCVA: best corrected visual acuity

EYP-1901 Phase 1 DAVIO clinical trial results at 6-months: mean CST is stable after single treatment



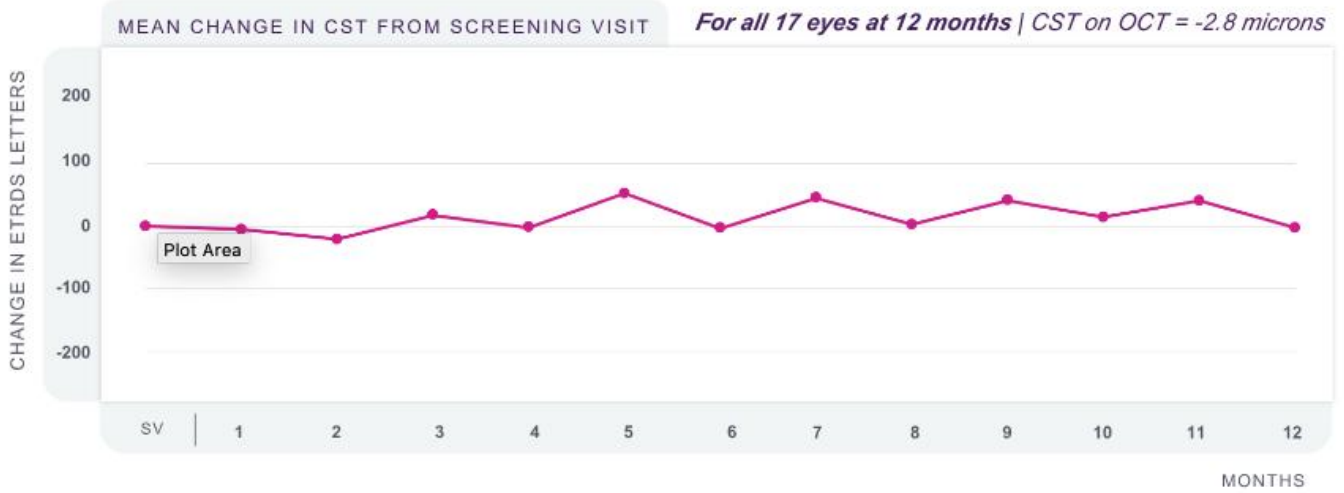
OCT: optical coherence tomography; CST: central subfield thickness

EYP-1901 Phase 1 DAVIO clinical trial results at 12-months: mean BCVA is stable after single treatment



BCVA: best corrected visual acuity; SV: screening visit

EYP-1901 Phase 1 DAVIO clinical trial results at 12-months: mean CST is stable after single treatment

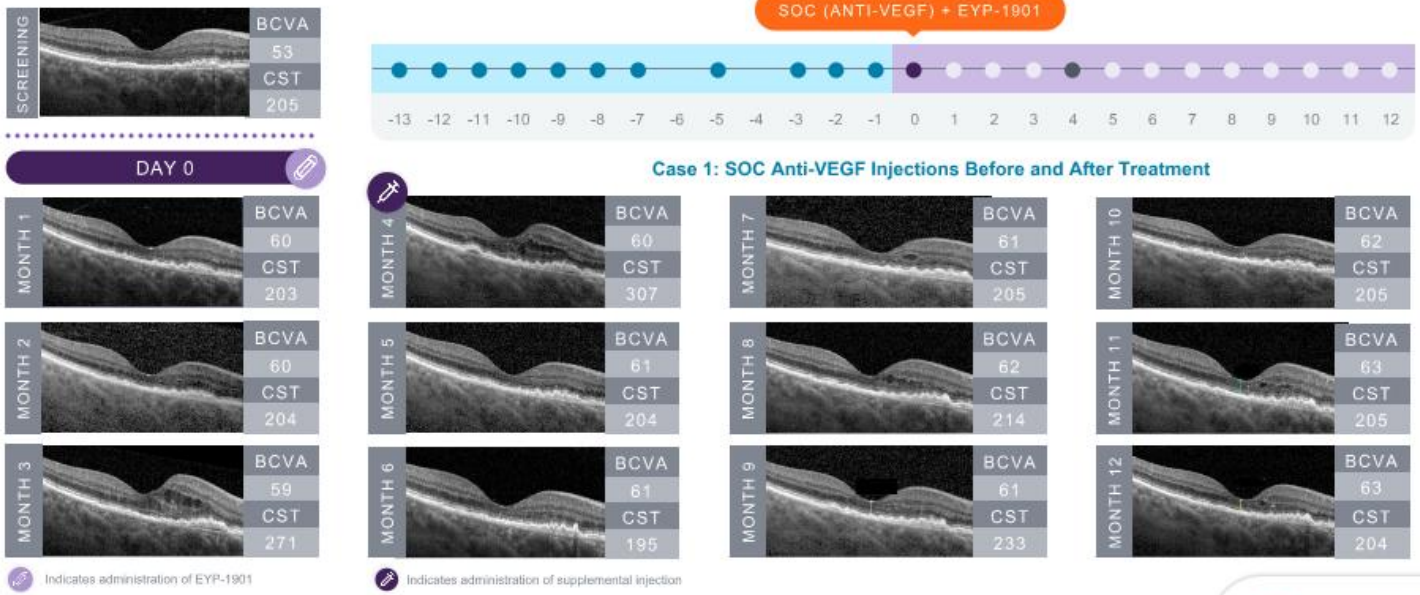


OCT: optical coherence tomography; CST: central subfield thickness

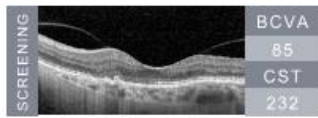
EYP-1901 Phase 1 DAVIO clinical trial demonstrated that 53% of patients did not require supplemental anti-VEGF treatment at 6-months



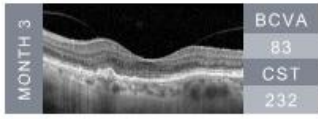
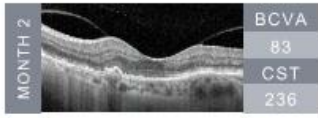
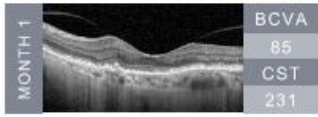
EYP-1901 Phase 1 DAVIO clinical trial case study, a mid-dose cohort patient remained dry after only one supplemental injection



EYP-1901 Phase 1 DAVIO clinical trial case study 2, a high-dose cohort patient remained dry after single EYP-1901 treatment



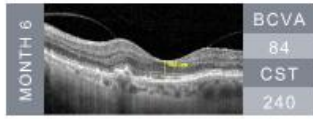
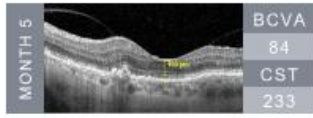
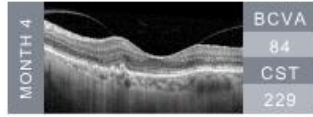
DAY 0



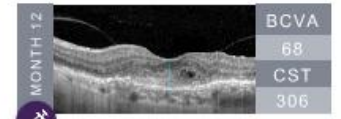
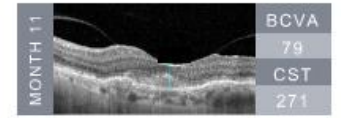
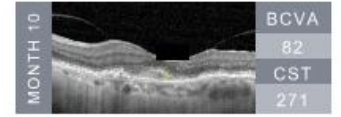
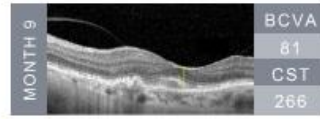
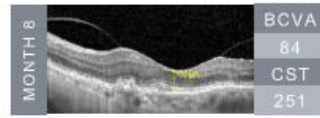
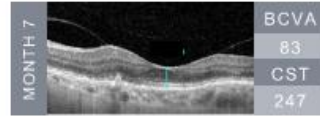
Indicates administration of EYP-1901



Case 2: SOC Anti-VEGF Injections Before and After Treatment



Indicates administration of supplemental injection



Indicates administration of supplemental injection

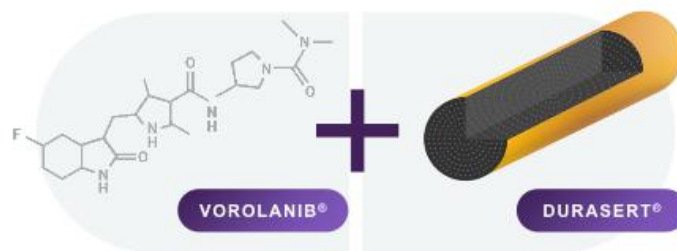
EYP-1901 Phase 1 DAVIO clinical trial met all objectives

FAVORABLE SAFETY PROFILE

- No ocular SAEs reported
- No drug-related systemic SAEs reported
- Ocular AEs – majority are mild and expected

POSITIVE EFFICACY & DURABILITY

- Stabilization of mean BCVA and OCT throughout 6 months was achieved
- 53% supplemental anti-VEGF injection free up to 6-months
- 79% reduction in treatment burden at 6-months



**SIX MONTHS MEDIAN TIME
TO SUPPLEMENTAL ANTI-
VEGF**

EYP-1901

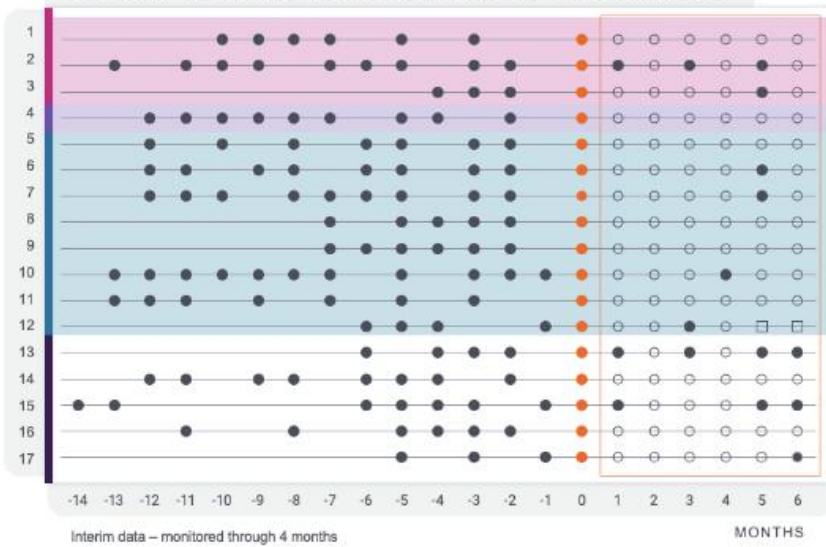
TREAT TO MAINTAIN

Jay Duker, M.D. | Chief Operating Officer

Charlie Wykoff M.D.

EYP-1901 demonstrated clinically significant reduction in treatment burden of 79% at 6 months supporting treat to maintain positioning

SOC ANTI-VEGF INJECTIONS BEFORE AND AFTER TREATMENT



TREAT TO MAINTAIN WITH EYP-1901

- About half of eyes in DAVIO could go up to 6 months on EYP-1901 alone
- Another ~30% received only a single supplemental anti-VEGF during 6-months
- About 15 % failed both SoC and 1901 and required multiple supplements

● Anti-VEGF ● SoC (Anti-VEGF)+ EYP1901
 ○ No rescue injection given □ Missed visit

EYP-1901 positioned as a potential “Treat-to-Maintain” therapy

- *Treat* initially with current anti-VEGF standard of care until VA is maximally improved and retina is as dry as possible (induction phase)
- *Maintain* with EYP-1901 every six months, supplementing if needed with current anti-VEGF biologic
- Based on DAVIO, we believe over half of all wet AMD eyes may be maintained visually and anatomically with EYP-1901 alone
- Another large segment may require occasional supplemental anti-VEGF but a much-reduced interval

Discussion on the potential clinical use of 1901 with Charlie Wykoff, M.D.

- If you had EYP-1901 available in your practice, how would you introduce it for your patients with wet AMD?
- What would like to see before you adopt it more broadly?
- Where do you see the value of a “Treat and Maintain” therapy in patients previously treated with an anti-VEGF therapy?
- Where do see the potential for EYP-1901 in the treatment of NPDR where currently approved anti-VEGF therapies are not widely adopted in patients with relatively good vision.
- What do you think about the potential use of EYP-1901 in other indications like DME or other VEGF-dependent conditions?

EYP-1901

PHASE 2 CLINICAL TRIAL PLANS

Wet AMD | NPDR

WET AMD PHASE 2 TRIAL (DAVIO 2)

Dario Paggiarino, M.D. | Chief Medical Officer

EYP-1901 DAVIO 2 clinical trial is non-pivotal randomized, double-masked, aflibercept controlled



EYP-1901 DAVIO 2 clinical trial design to evaluate two different doses with BCVA as primary endpoint

Objectives

Evaluate efficacy and safety of a single injection of two different doses of EYP-1901 in wet AMD reported.

01 Primary Endpoint
Mean change in BCVA at Week 32 (unmasking 6 months after EYP-1901)

02 Secondary Endpoints
CST, time to rescue, rescue-free rates, anti-VEGF injection burden

Duration of Follow-up 12 months following EYP-1901 injection at Week 8 (i.e., Week 56)

Key I/E Criteria

- Diagnosed within past 9 months
- History of response to anti-VEGF
- History of at least 2 injections in last 6 months
- OCT exclusion criteria:
 - ☒ Central subfield thickness > 400 μm
 - ☒ Intraretinal fluid >25 μm
 - ☒ Retinal pigment epithelium detachment thickness > 300 μm

EYP-1901 DAVIO 2 trial to evaluate supplemental anti-VEGF injections under strict criteria

Starting from Week 12

Criteria for supplemental aflibercept injections

- BCVA reduction of > 5 letters from best on study measurement due to wAMD AND Increase in CST of >75 microns on SD-OCT from lowest on study measurement
- BCVA reduction of ≥ 10 letters from best on study measurement due to wAMD
- Increase in CST of >100 microns on SD-OCT from lowest on study measurement from 2 consecutive visits
- Presence of new or worsening vision-threatening hemorrhage due to wAMD
- Or at the investigator's discretion

NPDR PHASE 2 CLINICAL TRIAL

Dario Paggiarino, M.D. | Chief Medical Officer

EYP-1901 Phase 2 NPDR clinical trial is non-pivotal, randomized double-masked, day-one single injection with sham control



EYP-1901 Phase 2 NPDR clinical trial primary endpoint is improvement of at least 2 DRSS* severity levels at week 36

Objectives

Evaluate efficacy and safety of a single injection of two doses of EYP-1901 in NPDR

- 01 **Primary Endpoint**
Improvement of at least 2 DRSS* severity levels at Week 36
- 02 **Secondary Endpoints**
Vision-threatening complications, occurrence of DME and/or proliferative disease (PDR), retinal ischemia/nonperfusion

Duration of Follow-up

48 weeks total duration of study

Key I/E Criteria Inclusion:

- Moderately severe to severe NPDR (DRSS 47-53)
- ETDRS letter score in the study eye of ≥ 69 letters (20/40)
- HbA1c%: $\leq 12\%$
- No anti-VEGF injections in the past 12 months

Exclusion:

- Presence of any active CI-DME in the central subfield, with a CST ≥ 320 microns

*diabetic retinopathy severity scale

PRODUCTS

YUTIQ CLINICAL UPDATES

Dario Paggiarino, M.D. | Chief Medical Officer

YUTIQ commercial franchise supported by ongoing CALM study with real-world data

The CALM study is a retrospective registry study to collect real-world data on patients treated with YUTIQ

Methods

- Data will be collected on up to 500 patients; 150 enrolled to date
- Routine standard of care assessments and adverse events will be recorded from routine visits over 5 years

Status

- Next data presentation updates planned for Retina Society 2022 and AAO 2022

YUTIQ commercial franchise also supported by anticipated Synchronicity phase 4 study

The Synchronicity study is evaluating YUTIQ's ability to attain complete remission of inflammation through control of macular edema

- First patient dosed in Q2 2022
- Initial data anticipated in 2H 2023

FINANCIAL UPDATE

George O. Elston | Chief Financial Officer

Solid cash position and growing revenues

Balance Sheet – June 30, 2022*

- \$171 million of cash and investments
- \$40 million of short and long-term debt

Financial Performance*

- \$11.3 million of net product revenues in Q2 2022, a 30% increase over Q2 2021
- Q2 2022 Customer demand
 - ~900 units of YUTIQ a 43% increase over Q1 2022
 - ~14,700 units of DEXYCU consistent with Q1 2022
- Commercial franchise projected to break-even in 2022
- Cash runway into 2H 2024 at current plan

* Q2 2022 financial results were calculated prior to the completion of a review by the Company's independent registered public accounting firm and are therefore subject to adjustment.

CMS Draft Hospital Outpatient Rule does not extend the pass-through status of expiring drugs impacting DEXYCU

- If draft rule is finalized as is, DEXYCU pass-through status will expire on December 31, 2022
- CMS clarified their intent to offer on-going pass through to non-opioid pain alternatives
- CMS clarified that they will require a pain indication in order for a product to be eligible for ongoing pass through
- Evaluating next steps for a potential DEXYCU pain indication

Q&A

CLOSING REMARKS
