UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): **November 2, 2023**

Ocuphire Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34079**	**11-3516358**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

37000 Grand River Avenue, Suite 120 Farmington Hills, MI 48335

(Address of principal executive offices and zip code)

248-957-9024
(Registrant's telephone number including area code)

(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**	**Name of Exchange on Which Registered**
Common Stock, par value $0.0001 per share	OCUP	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On November 2, 2023, Ocuphire Pharma, Inc. (the "Company") posted an updated corporate presentation to its website at https://ir.ocuphire.com/presentations, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Report.

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company's submission of this Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Exhibit 99.1 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 8.01 Other Events.

On November 2, 2023, the Company issued a press release announcing the successful outcome of an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, supporting the advancement of oral APX3330 for the treatment of diabetic retinopathy into Phase 3 studies based on the recently completed Phase 2 ZETA-1 trial.

A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation, dated November 2, 2023.
99.2	Press release issued by Ocuphire Pharma, Inc. on November 2, 2023.
104	Cover Page Interactive Data File (embedded within 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 hereunto duly authorized.

OCUPHIRE PHARMA, INC.

Date: November 2, 2023

By: /s/ Dr. George Magrath
Dr. George Magrath
Chief Executive Officer

Exhibit 99.1

Ocuphire PHARMA

Restore Vision & Clarity

November 2023

Ocuphire Corporate Presentation

Disclosures and Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning the success and timing of planned regulatory filings and approvals, pre-commercial activities, commercialization strategy and timelines, business strategy, product labels, cash runway, scalability, future clinical trials in presbyopia (P), dim light/night vision disturbance (DLD) and diabetic retinopathy (DR) / diabetic macular edema (DME), including the potential for Phentolamine Ophthalmic Solution (POS) to be a "best in class" presbyopia drop, and timing of planned future clinical trials for APX3330, APX2009 and APX2014, the advancement to Phase 3 registration path for APX3330, FDA agreement on Special Protocol Assessment, the success and timing of planned regulatory filings, business strategy, cash runway, scalability, the potential for APX3330 to be the most advanced and the first line of therapy for DR patients, and the potential market opportunity for and the ability of APX3330 to slow DR progression. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success, costs, and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) risks that the partnership with Viatris may not facilitate the commercialization or market acceptance of Ocuphire's product candidates; (ix) the success and timing of commercialization of any of Ocuphire's product candidates, including the scalability of Ocuphire's product candidates and (x) the maintenance of Ocuphire's intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by the Company from time to time with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

The Company makes no representation or warranty, express or implied, as to the accuracy or completeness of the information contained in or incorporated by reference into this presentation. Nothing contained in or incorporated by reference into this presentation is, or shall be relied upon as, a promise or representation by the Company as to the past or future. The Company assumes no responsibility for the accuracy or completeness of any such information. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

Ocuphire Pipeline

Product Candidate	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Regulatory Approval	Upcoming Milestones
APX3330 Oral Pill	Diabetic Retinopathy (DR)				SPA Submission		☑ EOP2 Mtg October 2023 ❑ Special Protocol Assessment (SPA) Submission
APX3330 Local Delivery	Retina						❑ Select retinal drug delivery technology
APX2009 and APX2014 Local Delivery	Retina						❑ Select retinal drug delivery technology
Phentolamine Ophthalmic Solution 0.75% Eyedrops	Pharmacologically-Induced Mydriasis	Partnered with Viatris					☑ **APPROVED (*RYZUMVI™*) *Sept 2023***
	Presbyopia (P)						❑ VEGA-2 Phase 3 Topline Data Q4 2023
	Dim Light or Night Vision Disturbances (DLD)						☑ SPA Submitted ❑ LYNX-2 2nd Phase 3 trial (n=150+)

Management Team with Decades of Drug Development Experience

George Magrath, MD, MBA
CEO

MUSC Medical University of South Carolina · The Citadel · Lexitas · Johns Hopkins University · Hovione · EDISON

Ronil Patel, MTech, MS
SVP, Operations and BD

Florida Tech · Betaliq · Revitalid · PointGuard · OCULOS Integrated Insight

Charlie Hoffmann, MBA
SVP, Corporate Development

Tuck School of Business at Dartmouth · Ocularis Pharma · Prudential · SynDevRx · Goldman Sachs

Amy Rabourn, CPA
SVP, Finance

Michigan Ross · Gemphire Therapeutics · Pfizer · NeuroBo Pharmaceuticals · pwc

Drey Coleman
VP, Clinical Operations

OCULOS Integrated Insight · SIRION Therapeutics · UCF

Mitch Brigell, PhD
Head, Clinical Development and Strategy

Kansas State University · aerpio · Pfizer · Novartis

Barbara Withers, PhD
VP, Clinical and Regulatory Strategy

Wayne State University School of Medicine · aerpio · GE · UBC · Pfizer

Bindu Manne
Head, Market Development and Commercialization

UNC Pembroke · Takeda · Shire · Merck · Ocular Therapeutix · equinox · ThromboGenics

Chris Ernst
Global Head, QA and Manufacturing

Northern Kentucky · aerpio · Akebia Therapeutics · MEDPACE

Laura Gambino
Director, Project Management

Eastern Michigan University · aerpio · Akebia Therapeutics · Pfizer

Daniela Oniciu, PhD
Global Head, R&D, Chemistry and Product Development

UF University of Florida · Gemphire Therapeutics · Esperion · Cerenis Therapeutics · Pfizer

Corporate Highlights

Late-Stage Clinical Candidate for Retinal Diseases Represents Multi-Billion Dollar Opportunity

APX3330: *Paradigm Changing, Non-invasive, Safe Oral Tablet for millions of NPDR patients that are currently left untreated*

- *Ref-1, a novel, dual target (angiogenesis and inflammation) for retinal diseases*
- *ZETA-1 Phase 2 showed APX3330 prevented or slowed progression of Diabetic Retinopathy (DR)*
- *Successful EOP2 meeting with the FDA and a Special Protocol Assessment (SPA) to be submitted*

Phentolamine Ophthalmic Solution 0.75% (POS) for Refractive Disorders

- Global license agreement with Viatris to fund all development and commercialization for phentolamine indications:
  - ***RYZUMVI™ (Phentolamine Ophthalmic Solution) 0.75% for the treatment of pharmacologically-induced mydriasis received FDA approval in September 2023***
    - *Approval triggered $10M milestone payment*
  - ***Presbyopia*** *and* ***Dim Light Disturbances*** *currently in Phase 3*

Experienced Retina Drug Development Team to Advance APX3330 into Phase 3

Diabetic Retinopathy Market and Unmet Need

Diabetic Eye Disease is a Common Cause of Blindness

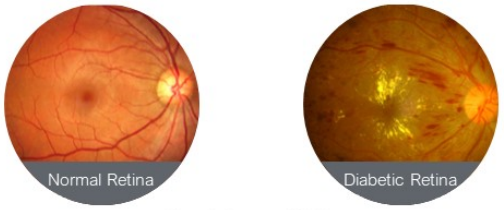
Diabetes and Diabetic Retinopathy (DR)

Diabetes Mellitus is a group of diseases characterized by high blood glucose levels. Diabetes results from defects in the body's ability to produce and/or use insulin

Type 1 diabetes (T1D): The body produces very little or no insulin, which means that patients need daily insulin injections to maintain blood glucose levels

Type 2 diabetes (T2D): The most common form of diabetes - either the body does not produce enough insulin, or resists insulin

Diabetic retinopathy (DR) occurs when fluctuations or instability in blood glucose levels damages blood vessels in the retina



Two Types of DR

Non-Proliferative Diabetic Retinopathy (NPDR) – most common form of DR – early stages of edema and exudates, blurred central vision

Proliferative Diabetic Retinopathy (PDR) – later stage of DR, marked by abnormal blood vessels and scar tissue on retina

Diabetic Macular Edema (DME) can occur at any stage of DR

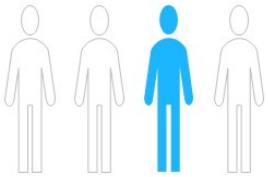
https://webeye.ophth.uiowa.edu/eyeforum/tutorials/diabetic-retinopathy-med-students/Classification.htm
https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/symptoms-causes/syc-20353011
https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193

Diabetic Retinopathy at a Glance

Current Treatment Landscape Demonstrates Need for Non-Invasive Therapies

There are **~8M** adults in the U.S. with NPDR

The number of people with DR expected to increase more than **14M** by 2050

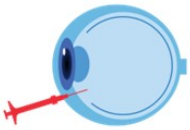


DR is the **leading cause of blindness** among working-age adults with the median age of onset at 45 – 50 years

Physicians have **no non-invasive options for NPDR** with current standard being wait-and-monitor

Prevention of Progression is favored by payors with chronic diseases such as diabetes which is the primary driver of increased healthcare costs

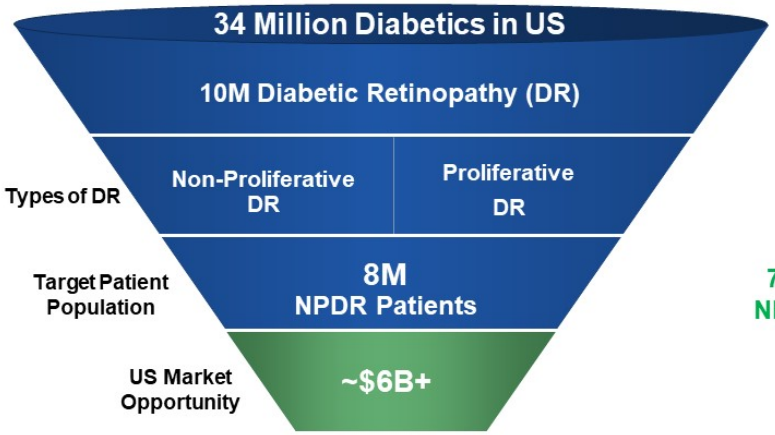
Majority of moderate to severe patients with DR are **not treated with anti-VEGF due to injection burden and no benefit to visual acuity**



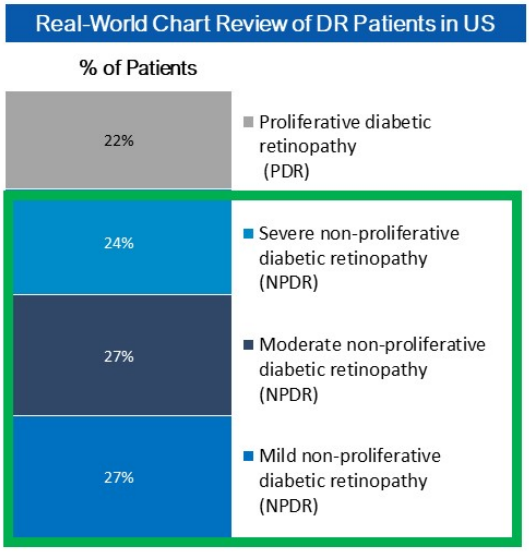
American Diabetes Association; International Diabetes Federation; Healthline; *Ocuphire internal analysis and assumptions
Das UN. DME, retinopathy and age-related macular degeneration as inflammatory conditions. Arch Med Sci. 2016;12(5):1142-1157. doi:10.5114/aoms.2016.61918
Patient survey adapted from Lions International Foundation and International Diabetes Foundation-Europe; Meltzer 2000
Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020) AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema ; BRVO = Branch Retinal Vein Occlusion
National Center for Chronic Disease Prevention & Health Promotion. Health & economic costs of chronic diseases. Atlanta (GA): Centers for Disease Control & Prevention, US Department of Health and Human Services; 2018
Four-Year Visual Outcomes in a Randomized Trial of Intravitreous Aflibercept for Prevention of Vision Threatening Complications of Diabetic Retinopathy (Protocol W)." JAMA. February 7, 2023

U.S Diabetic Retinopathy Market

Majority of the DR Patients are NPDR Severity → Target Population for APX3330



78% NPDR

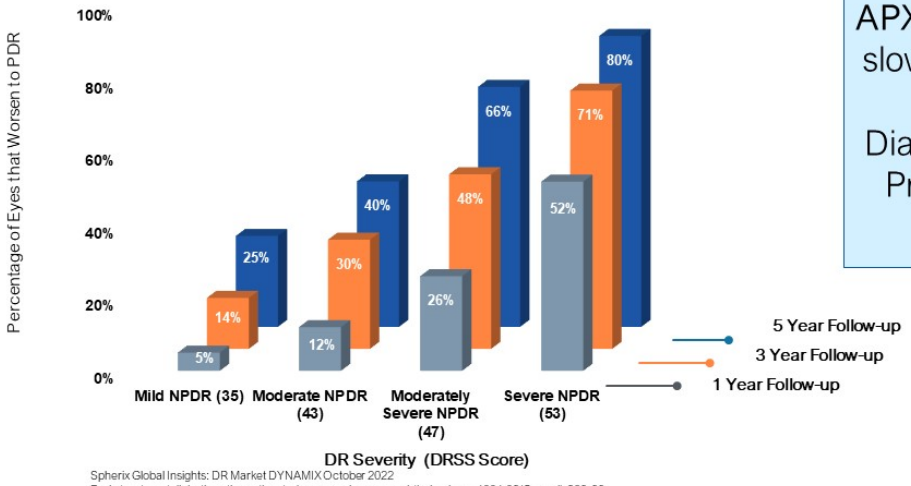


American Diabetes Association; International Diabetes Federation; Healthline; *Ocuphire internal analysis and assumptions; Spherix Global Insights
Patient survey adapted from Lions International Foundation and International Diabetes Foundation-Europe; Meltzer 2000
Estimates are provided by the National Eye Institute, FactSheet, Global Data, and Research and Markets. Estimated values are rounded.
Estimated prevalence in the U.S.; DME- Diabetic Macular Edema; Age-related Macular Degeneration; Geographic Atrophy; Retinal Vein Occlusion

Progression of DR Severity Measured up to 5 Years

NPDR Patients are Rarely Treated with anti-VEGF Intravitreal Injections Due to Treatment Burden

Regardless of severity, all eyes worsen over time



Early Intervention with **APX3330** can potentially slow the **progression** of Non-Proliferative Diabetic Retinopathy to Proliferative Diabetic Retinopathy

Spherix Global Insights: DR Market DYNAMIX October 2022

Early treatment diabetic retinopathy study research group. ophthalmology. 1991;98(5 suppl):823-33.

Diabetes control and complications trial research group. N Engl J Med. 1993;329(14):997-86.

Fathy C, Patel S, Sternberg P Jr, Kohanim S. Disparities in adherence to screening guidelines for diabetic retinopathy in the United States: a comprehensive review and guide for future directions. *Semin Ophthalmol.* 2016;31(4):364–377. doi: 10.3109/08820538.2016.1154170

Diabetic Retinopathy Treatment Landscape

Current Standard of Care Based on Severity

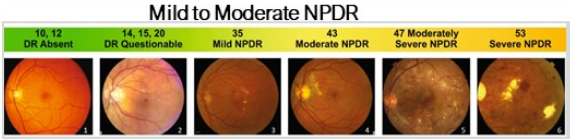
Currently, There Are No Non-Invasive Treatments Approved for Early Intervention or Slowing the Progression

2021 ASRS PAT Survey

Closely monitor retinopathy and encourage systemic glycemic control

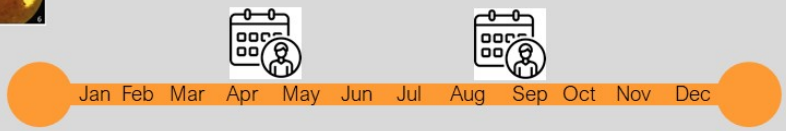
59.5%
60.5%

Mild to Moderate NPDR

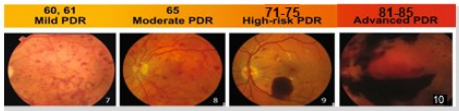


NPDR patients are monitored for progression requiring visits to the office every 4-6 months

Wait and Monitor for Progression



PDR



Gold standard Eylea® and Lucentis® injections are effective treatments in the first year for PDR

Anti-VEGF Injections

Ocuphire

Landscape of Investigational Non-Invasive Therapies for Diabetic Retinopathy

Ocuphire's APX3330 is the Most Advanced Oral Drug Candidate

Company	Drug	Target/MOA	Indication	Route of Administration	Phase 1	Phase 2	Phase 3	Primary Endpoint/ Secondary Endpoints
Ocuphire	APX3330	Ref-1 inhibitor (Anti-angiogenesis & Anti-inflammatory)	DR	Oral	✓	✓ 2022		2020: 2-step DRSS @wk24
Roche	RG7774	CB2 receptor (cannabinoid)	DR	Oral	✓	X 2023		2020: 2-step DRSS @wk36
Bayer	BAY1101042	Guanylate Cyclase activator	DR	Oral	✓	○		2021: 2-step DRSS @wk24
Valo	OPL-0401	ROCK 1/2 inhibitor	DR	Oral	✓	○		2021: 2-step DRSS @wk24
Vantage	VX-01	AOC-3 inhibitor	DR	Oral	✓	○		2022: Not Disclosed
OcuTerra Therapeutics	OTT166	Integrin inhibitor	DR	Eyedrop	✓	○		2022: 2-step DRSS @wk24

Note: Two Tyrosine Kinase and a Plasma Kallikrein Inhibitors failed as orals in Phase 2 due to dose limiting adverse events (e.g., liver and cardiovascular)

✓ *Completed* ○ *Ongoing* × *Discontinued*

APX3330 is the ONLY candidate with validated retinal pathways of angiogenesis and inflammation.

Human exposure >10,000 subject days of systemic exposure at 600mg/day dose and a **favorable safety and tolerability profile.**

Landscape of Invasive Therapies (IVT/Suprachoroidal) for Diabetic Retinopathy

Eylea®/Lucentis® Approved, But Not Used in Patients with NPDR; Rarely Used in Mild PDR

Company	Drug	Target/MOA	Route of Administration	Phase 1	Phase 2	Phase 3	Commercial
REGENERON	Eylea® (aflibercept)	VEGF-A/B; PIGF	Intravitreal	✓	✓	✓	✓*[1]
Roche	Lucentis® (ranibizumab)	VEGF-A	Intravitreal	✓	✓	✓	✓*[2]
KODIAK	KSI-301 (Tarcocimab)	VEGF	Intravitreal	✓	N/A	○	
EyePoint Pharmaceuticals	EYP-1901	Voloronib* (TKI)	Intravitreal	✓	○		
Boehringer Ingelheim	BI 764524	Anti-Sema3A Ischemia modulator	Intravitreal	✓	○		
Ocular Therapeutix	OTX-TKI	Axitinib* (TKI)	Intravitreal	✓	○		
REGENXBIO	RGX-314	AAV8-VEGF	Suprachoroidal (Gene Therapy)	✓	✓		

* Failed as oral/systemic treatments in retina due to dose limiting toxicity

✓ Completed ○ Ongoing X Discontinued

*Trials to Support Approval
[1] Panorama Clinical Trial
[2] Protocol I & T and Rise & Ride

Ocuphire Pharma

Company websites and www.clinicaltrials.gov (as of October 31, 2023)

APX3330 Background

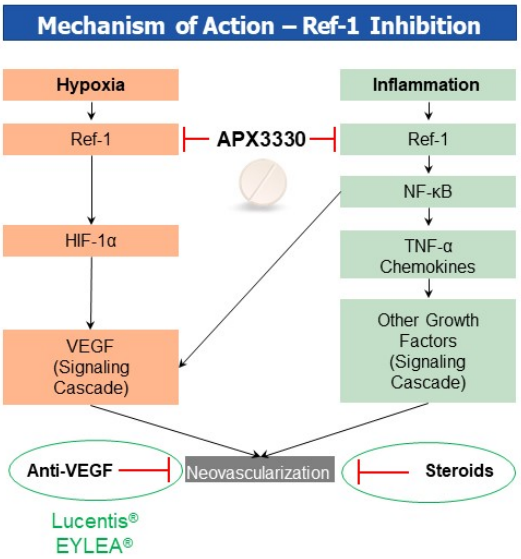
APX3330 - Mechanism of Action Targeting Ref-1 Inhibition

Ref-1 Involved in Key Pathways that Contribute to Diabetic Retinopathy and Diabetic Macular Edema

Ref-1 (reduction-oxidation effector factor-1)

A novel target for retinal diseases, is a transcription factor regulator of angiogenesis (VEGF) and inflammation (NFkB)

- **Unique MOA decreases abnormal angiogenesis and inflammation**
  - APX3330 does not deplete the VEGF levels but rather normalizes VEGF levels to physiologic levels
- **Anti-VEGF injections *do not* target inflammation**



Logsdon et al (2018), Li et al (2014).

APX3330: Drug Development History and Patents

Significant Preclinical & Clinical Data Supporting Human Safety, MOA, and PK

APX3330
New Chemical Entity

12*
Phase 1 & Phase 2 Trials

Exposure in Humans
>10,000
Subject Days at 600mg/day

Patents to
2035+

Studied in inflammation/hepatitis & cancer patients
(Studied by Eisai & Apexian, respectively)

Focus on Ophthalmology

- Previously developed by Eisai for hepatic inflammatory indications and by Apexian for solid tumors in **11 Phase 1 and 2 trials**
- Extensively studied in over **20 in-vitro and animal studies** with favorable efficacy and safety results

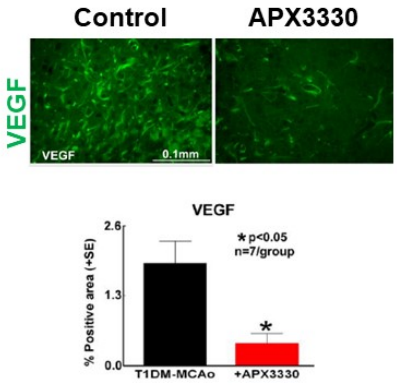
Ocuphire

Includes ZETA-1 trial

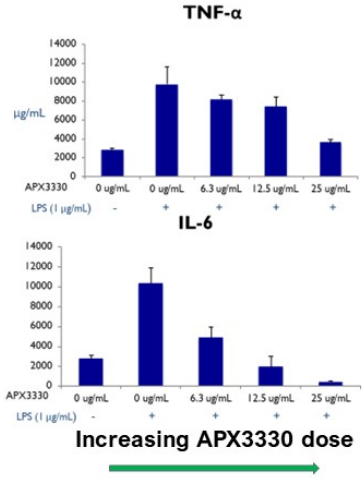
In-vitro Validation of Mechanism of Action

APX3330 Reduces VEGF levels and Inflammatory Cytokines; Provides Neuronal Protection

APX3330 reduces VEGF protein expression in preclinical stroke model

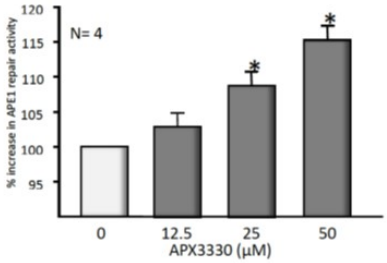


APX3330 reduces pro-inflammatory cytokines in LPS stimulated macrophages



Increasing APX3330 dose

APX3330 increases DNA oxidative repair and neuronal protection



APX3330 enhances Ref-1 endonuclease activity in dorsal root ganglion neurons

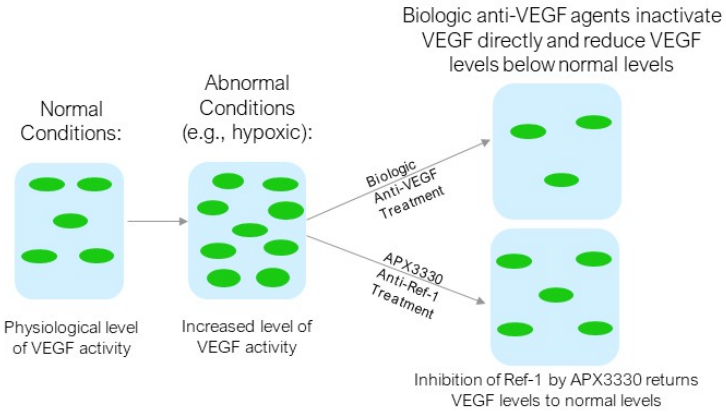
Tao Yan *et al.* APX3330 Promotes Neurorestorative effects after stroke in type one diabetic rats. Aging and Disease. Vol 9, Oct 2018

Apurinic/Apyrimidinic endonuclease 1 regulates inflammatory response in macrophages. Jedinak A, Dudhgaonkar S, Kelley MR, Sliva D. Anticancer Res. 2011 Feb;31(2):379-85. PMID: 21378315

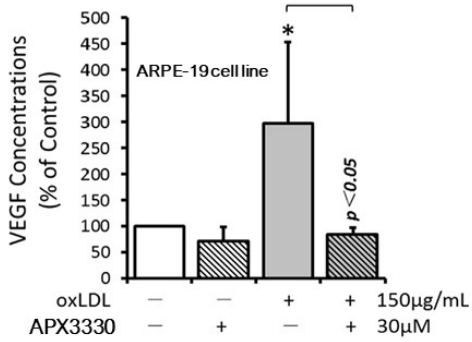
Fehrenbacher, J. C., Guo, C., Kelley, M. R. & Vasko, M. R. DNA damage mediates changes in neuronal sensitivity induced by the inflammatory mediators, MCP-1 and LPS, and can be reversed by enhancing the DNA repair function of APE1. Neuroscience 366, 23-35, doi:10.1016/j.neuroscience.2017.09.039 (2017)

APX3330 VEGF Effects in Normal Cells

APX3330 Restores Normal Levels Unlike Biologic Anti-VEGFs that Reduce VEGF Below Normal



APX3330 prevents VEGF overproduction in ARPE-19 cells



- VEGF is a growth factor that is necessary for normal function of multiple cell types including vascular endothelium and neurons ➔ By returning VEGF levels to normal, APX3330 can reduce neovascularization, vascular leakage and the inflammatory response without adverse systemic effects
- The safety profile of APX3330 to date has not shown any of the adverse effects that has been seen with systemic administration of anti-VEGF biologics such as cardiovascular pathology, hypertension, arteriothrombotic events, or renal dysfunction

Ocuphire

Kamba 2007; Girardi 2010; Li 2014
APX3330 Investigator Brochure

APX3330 ZETA-1 Clinical Trial

ZETA-1: Phase 2 Trial of Oral APX3330 in Subjects With Diabetic Retinopathy

Multi-center, Randomized, Double-Masked, Placebo-Controlled 24-Week Trial

Eligibility Criteria

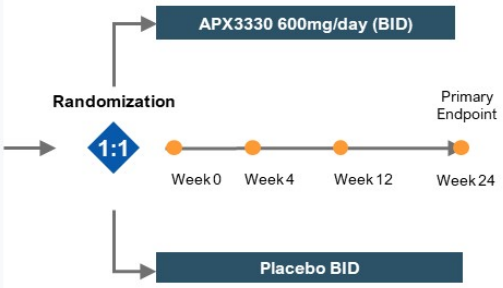
- 25 US sites
- N = 103 participants with moderately severe to severe NPDR or mild PDR (DRSS 47, 53, 61)

Key inclusion:

- ≥ 18 years of age
- DRSS 47, 53, or 61
  - Noncentral DME permitted[2]
- ETDRS BCVA ≥ 60 letters (20/63)

Key exclusion:

- OCT CST >320 µm[2]
- Center involved DME allowed in fellow eye
- Anti-VEGF within past 6 months[3]
- HbA1c ≥ 12.0%



Endpoints

Primary:

- % subjects with ≥ 2 step improvement on DRSS (Diabetic Retinopathy Severity Scale[1]) at week 24

Secondary:

- DRSS improvement ≥1, ≥2, ≥3, ≥4 study eye, fellow eye, binocular
- DRSS worsening ≥1, ≥2, ≥3, ≥4, study eye, fellow eye, binocular
- Progression to vision threatening complications
- Central subfield thickness (CST)
- Best Corrected Distance Visual Acuity (BCDVA)
- DME fellow eye status
- Safety and tolerability

Exploratory:

- Inflammatory cytokines

103 subjects enrolled (FPFV Apr 2021 to LPLV Aug 2022)
Topline data announced in January 2023

1. *By Central Reading Center*
2. *Center-Involved DME in Fellow Eye is Acceptable*
3. *Includes Systemic or IVT VEGF*

www.clinicaltrials.gov (NCT04692688); Eylea® is registered trademark of Regeneron
NPDR = non-proliferative diabetic retinopathy PDR = proliferative diabetic retinopathy

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ZETA-1: Baseline Demographics and Systemic Characteristics

Well-Balanced Across Arms

Demographics

	APX3330 n=51	Placebo n=52
Age (years) mean (range)	54.3 (26-81)	58.3 (24-78)
Sex: Male n (%)	24 (47%)	26 (50%)
Race: White n (%)	40 (78%)	41 (79%)
Ethnicity: Hispanic or Latino n (%)	28 (55%)	23 (44%)
Diabetes Status (years) mean (range)	15 (0-36)	16 (0-58)
Systolic Blood Pressure (mmHg) mean	136	139
Diastolic Blood Pressure (mmHg) mean	82	80
Heart Rate (beats/min) mean	77	76
Hemoglobin A1C (%) mean	8.4	8.3
Body Mass Index (kg/m^2) mean	31	31

DRSS Scores

	APX3330 n=49	Placebo n=52
DRSS Score – Study Eye		
47 (Moderately severe to severe NPDR)	22 (43%)	18 (35%)
53 (Moderately severe to severe NPDR)	25 (49%)	28 (54%)
61 (Mild proliferative diabetic retinopathy)	4 (8%)	6 (12%)
DRSS Score – Fellow Eye		
43 or Lower (Mild to moderate NDPR or better)	**15 (31%)**	**13 (25%)**
47 (Moderately severe to severe NPDR)	15 (31%)	20 (38%)
53 (Moderately severe to severe NPDR)	12 (25%)	10 (19%)
61 (Mild proliferative diabetic retinopathy)	1 (2%)	4 (8%)
65 or Higher (Moderate to severe prolif. DR)	**6 (12%)**	**5 (10%)**

Note: 15 fellow eyes were CST>320 microns (center-involved DME eyes)

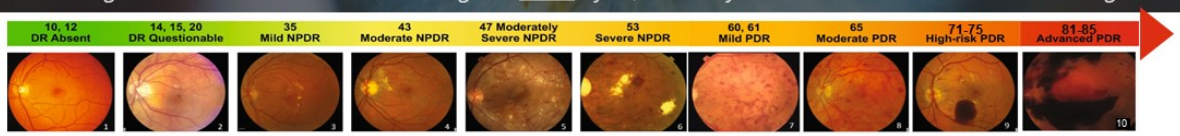
Key Visual Metrics

	APX3330 n=51	Placebo n=52	Total n=103
BCVA Study Eye *Letters (mean)*	**81**	**78**	**80 (20/25 Snellen)**
BCVA Fellow Eye *Letters (mean)*	76	77	77 (20/32 Snellen)
OCT CST Study Eye *(µm)*	**270**	**271**	**271**
OCT CST Fellow Eye *(µm)*	292	286	289
Intraretinal Fluid in the Center of SE	Y – 21 N – 26	Y – 12 N – 31	Y – 33 N – 57
Intraretinal Fluid at the Foveal Center of SE	Y – 1 N – 20	Y – 1 N – 11	Y – 2 N – 31
Intraocular Pressure in Study Eye (mmHg)	15	16	15

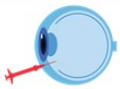
Good Visual Acuity / Fluid Below 320µm

Clinically Meaningful Registration Endpoints in DR

*Systemic Drugs Should Evaluate DRSS Change in **Both** Eyes; Formally Confirmed at EOP2 FDA Meeting*



FDA accepts improvement OR worsening (slowing or prevention of progression)[1] of the disease AND DRSS is an established surrogate endpoint for DR



Local Drugs (Intravitreal Injections)

Precedent approvable endpoint for locally-delivered drugs (non-systemic) in DR:

- ≥ 2-step DRSS improvement in study eye
  - Aflibercept (PANORAMA trial)
  - Ranibizumab (RISE/RIDE trials)

Systemic Drugs

Approvable endpoints for systemic drug in DR include either:

- ≥ 3-step DRSS improvement on a binocular scale
- ≥ 3-step DRSS worsening on a binocular scale

For oral administration, the binocular DRSS endpoint is distinct from anti-VEGF IVT precedent due to different delivery

Source: ZETA-1 Clinical trial

1. Nair P, Aiello LP, Gardner TW, Jampol LM, Ferris FL III. Report From the NEI/FDA Diabetic Retinopathy Clinical Trial Design and Endpoints Workshop. Invest Ophthalmol Vis Sci. 2016 Oct 1;57(13):5127-5142. doi: 10.1167/iovs.16-20356. PMID: 27699406; PMCID: PMC6016432.

End-of-Phase 2 Meeting Outcome

FDA Accepts the Binocular DRSS Person Scale For Phase 3 APX3330 DR Program

DRSS is a Validated Surrogate Endpoint

Level (worse eye/better eye)	Description	Scale Step
10/10	No DR	1
20/<20 20/20	Microaneurysms only, one or both eyes	2-3
35/<35 35/35	Mild NPDR, one or both eyes	4–5
43/<43 43/43	Moderate NPDR, one or both eyes	6-7
47/<47	Moderately severe NPDR, one eye	8
47/47	Moderately severe NPDR, both eyes	9
53/<53	Severe or very severe NPDR, one eye	10
53/53	Severe or very severe NPDR, both eyes	11
60 or 61/<60	Mild PDR and/or SPC, one eye	12
60 or 61/60 or 61	Mild PDR and/or SPC, both eyes	13
65/<65 65/65	Moderate PDR, one or both eyes	14-15
71+/<71 71+/71+	High risk PDR, one or both eyes	16-17+

In the binocular Person Scale, the worse eye is weighted instead of calculating the sum of both eyes

A 3-step change on this scale is considered clinically meaningful by FDA

Baseline 47,43 = Step 8

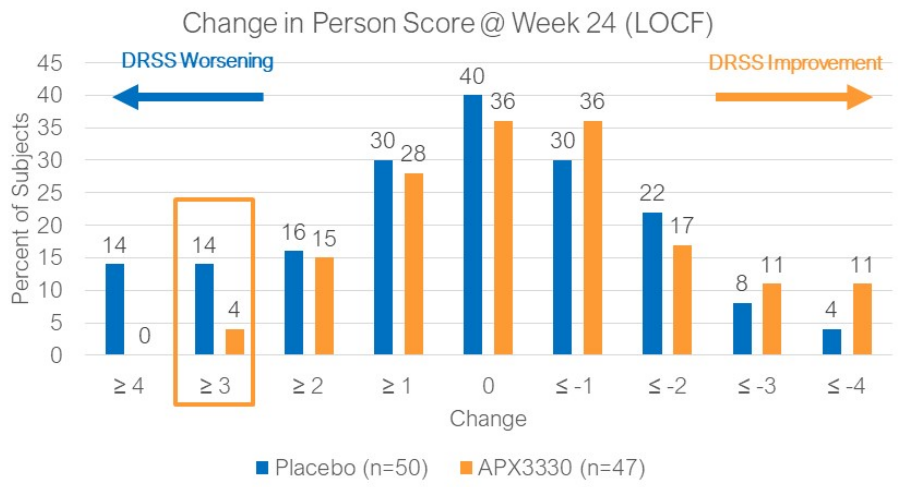
Final 47,47 = Step 9 (1-step change)

Final 53,43 = Step 10 (2-step change)

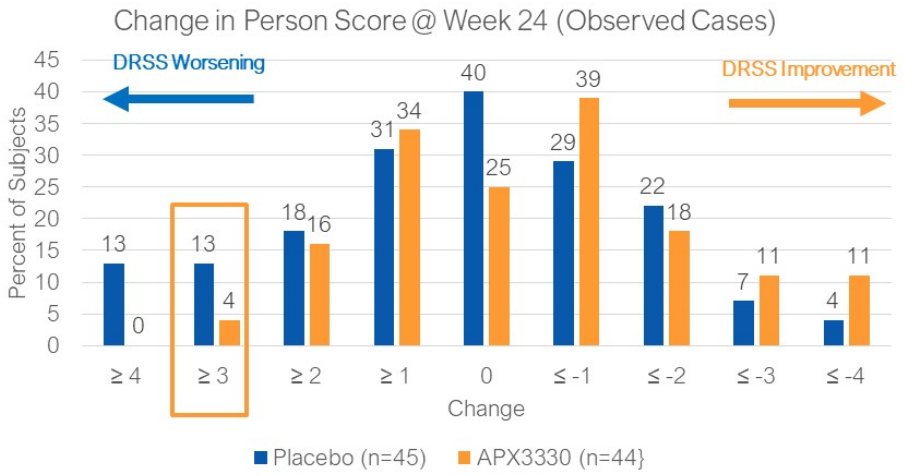
Final 61,43 = Step 12 (4-step change)

Final 61,53 = Step 12 (4-step change)

ZETA-1: Percent of Subjects with Improvement or Worsening in DRSS at Wk 24 on the Binocular Person Scale (LOCF)



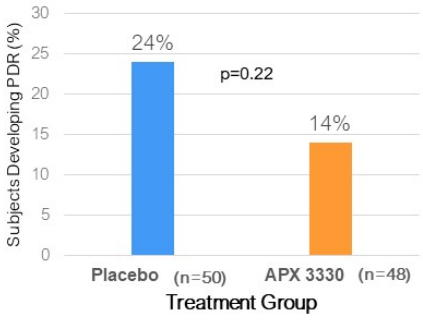
ZETA-1: Percent of Subjects with Improvement or Worsening in DRSS at Wk 24 on the Binocular Person Scale (Observed Cases)



APX3330 Reduced % of Subjects Developing PDR and % Losing BCVA

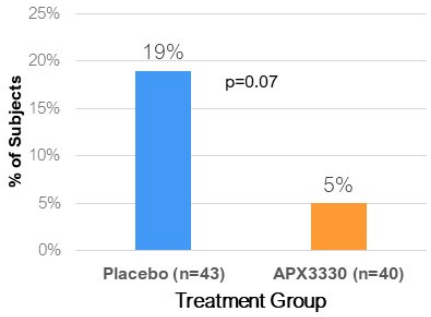
APX3330 Prevented Progression of Structural Retinal Abnormalities

Percentage of Subjects Developing PDR (mITT Population) at week 24



APX3330 reduced the percentage of subjects who developed PDR over the course of 24 weeks

Percentage of Subjects with ≥ 5 Letters of BCVA Lost at Week 24 (Safety Population)



BCVA data shows **fewer APX3330 treated subjects losing visual acuity** compared to placebo at week 24

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ZETA-1 Clinical Trial.

ZETA-1: Treatment of Emergent Adverse Events

Oral APX3330 Showed a Favorable Safety and Tolerability Profile Consistent with Prior Trials

	Placebo (n=52)	APX3330 (n=51)
Total AEs	120	91
#of Subjects with AEs	35 (67%)	29 (57%)
Treatment-related AEs	17 (14%)	14 (15%)
Serious AEs	11 (9%)	3 (3%)
Subjects Withdrawals Due to AEs	1 (2%)	2 (4%)
Deaths	1 (2%)	0 (0%)
AEs in >5% of Subjects*		
Eye disorders | Diabetic Retinal Edema	5 (10%)	2 (4%)
Diabetic Retinopathy	6 (12%)	1 (2%)
Vitreous detachment	3 (6%)	0 (0%)
Cataract	1 (2%)	3 (6%)
Pruritus	1 (2%)	6 (12%)
Rash	1 (2%)	3 (6%)
COVID-19	5 (10%)	1 (2%)

APX3330 Safety Profile:

- Limited AEs, most mild in severity
  - Pruritis: Mild and resolved without APX3330 dose de-escalation or discontinuation
- AEs similar to or less than placebo
- Few serious treatment-related AEs, all unrelated to study medication
- No ocular AEs other than expected DR progression
  - Lower incidence of clinical DR/DME worsening with APX3330
- **Patients continued routine medications to manage their diabetes comorbidities**

APX3330 SAEs: Dyskinesia, TIA, Chest pain
Placebo SAEs: Vertigo, Asthenia, Multiple organ dysfunction, Bradycardia, CAD, Cholelithiasis, COVID-19 pneumonia, Cellulitis, Respiratory failure, Skin ulcer, Peripheral embolism
AEs → Withdrawal APX3330: Presyncope, Dyspnea; Placebo: DME (both eyes)
*Preferred Term within Organ Class

APX3330 Summary

APX3330 Milestones

- Successful EOP2 FDA meeting completed in October 2023; agreement that a 3-step change on the binocular person scale is an approvable registration endpoint
- Submit Special Protocol Assessment (SPA)
- Advance APX3330 into Phase 3 program with long-term exposure (up to 2 years)

Our Goal for Patients To have a clinically meaningful impact on ***slowing or preventing progression*** to reduce likelihood of vision loss in diabetic retinopathy patients

DR and APX3330 Key Takeaways

- DR is one of the largest markets in retina with 10M patients in US and over 100M worldwide
- Majority of the NPDR patients are not candidates for approved biologics treatments and are left untreated
- APX3330 first-in-class oral drug with unique MOA that inhibits Ref-1 which reduces VEGF and inflammatory cytokines to normal physiological levels
- Prevention of worsening is a clinically meaningful potential registration endpoint
- APX3330 demonstrated favorable safety and tolerability in diabetic patients
- **Successful EOP2 meeting with the FDA and a Special Protocol Assessment (SPA) to be submitted**
- APX3330 has the potential to be an early, non-invasive preventative treatment for the 8 million NPDR patients with the potential to treat other organs affected by diabetes (e.g., kidney disease, peripheral neuropathy)
- Broad prescriber base including general ophthalmology, optometry and primary care due to favorable safety

Phentolamine Ophthalmic Solution 0.75%

Global Partnership with Viatris for Phentolamine Ophthalmic Solution 0.75%

Viatris Has Selected POS to be a Key Element of its Global Eye Care Division

Partner for global commercialization

Fully funded development and commercialization costs for all 3 phentolamine indications

Allows Ocuphire to focus on APX3330 development

Strengthens cash position into 2025

- **$35 million upfront**
- **Fully funded development and commercialization for all 3 indications**
- **$130 million in regulatory and sales milestones**
  - First milestone payment of $10 million on FDA approval for pharmacologically-induced mydriasis indication
- **Tiered double digit royalties through 2040**

Treatment of Pharmacologically-Induced Mydriasis

APPROVED

RYZUMVI™ (Phentolamine Ophthalmic Solution) 0.75% for the Treatment of Pharmacologically-Induced Mydriasis Produced by Adrenergic Agonists (e.g., Phenylephrine) or Parasympatholytic (e.g., Tropicamide) Agents

Presbyopia

1 POS as a Single Drop

2 POS with LDP Adjunctive Therapy

Dim Light or Night Vision Disturbances (DLD)

Summary of Phentolamine Ophthalmic Solution 0.75% Trial Results

Comprehensive Body of Clinical Data Supporting Efficacy and Safety Across 3 Indications

Indication & Status	Primary Endpoint	Efficacy Data	Key Secondary Endpoint(s)	Safety & Tolerability
Ryzumvi™ **Approved September 2023**	Return to baseline pupil diameter at 90 minutes after dilation	**Met Phase 3 primary endpoint** **MIRA-3**: 58% POS vs. 6% placebo **MIRA-2**: 49% POS vs. 7% placebo (p<0.0001) **MIRA-4**: 64% POS vs. 25% placebo	Efficacy across all mydriatic agents, iris color, 1 or 2 drops, and all ages (3-80)	• No headaches • No blurry vision • ~5% mild redness • No change in IOP • No SAEs • Most AEs were mild
Presbyopia (POS Alone) **Phase 3**	≥3 line gain in near vision with loss of no more than 1 line in distance vision	**Met planned Phase 3 primary endpoint** **VEGA-1**: 29% POS vs.12% placebo at 12 hrs post-POS dose (p=0.02)	Durable near vision (18 hrs) Optimal pupil size Pupillary light reflex	
Presbyopia (POS + LDP) **Phase 3**		**Met Phase 2 primary endpoint** **Met planned Phase 3 primary endpoint** **VEGA-1**: 61% combo post-LDP dose (30 min) + post-POS dose (12 hrs) vs. 14% placebo (p<0.0001)	Durable near vision gain Optimal pupil size Pupillary light reflex	
DLD **2nd Phase 3**	≥3 lines (eye test) of improvement in mesopic low contrast best-corrected distance visual acuity (mLCVA)	**Met Phase 3 primary endpoint** **LYNX-1**: 13% POS vs. 3% placebo at Day 8 (p<0.05) and 21% in POS vs.3% placebo at Day 15 (p<0.01)	Improvement visual acuity measures (distance and near) in dim light conditions	

Corporate Highlights

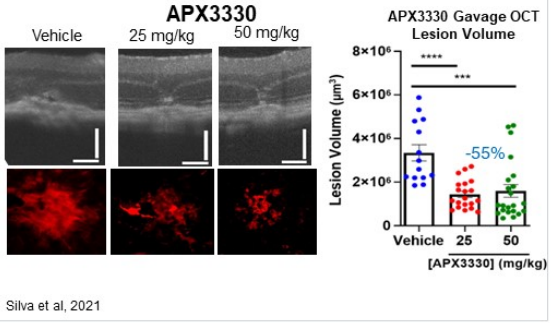
- ***Late-Stage Retinal Pipeline*** *Represents* ***Multi-Billion Dollar Opportunity*** *in Unmet NPDR Patients*
- ***APX3330 – Novel, Non-Invasive, Safe Oral Tablet*** *to Treat Diabetic Retinopathy*
- *APX Pipeline Driven by a* ***Paradigm Changing, Dual Target Ref-1 Platform*** *for Retinal Diseases*
- ***Global License Agreement with Viatris*** *to Fund Development and Commercialization of Phentolamine Ophthalmic Solution 0.75% for All Refractive Indications*
- ***Strong Financial Position*** *to Fund Operations into 2025*

Preclinical Data: Oral APX3330 Blocks Neovascularization

Lesion Volume Decrease with Oral APX3330 in Murine Laser CNV Model Similar to EYLEA® Data

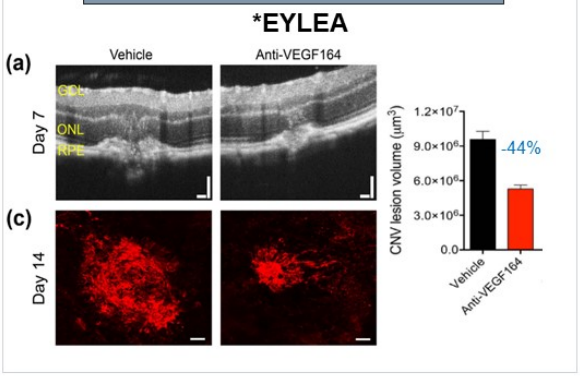
L-CNV Mouse Retina Model

Lesion Size and Corresponding Fluorescent Stains in L-CNV Models Treated with APX3330 at 25 mg/kg oral gavage



Silva et al, 2021

L-CNV Mouse Retina Model



- ✓ **Efficacy was also seen after single <u>intravitreal</u> injection of 20µM APX3330 in mouse L-CNV model****
- ✓ **Efficacy was also seen after dosing <u>intraperitoneal</u> injection of 50 mg/kg twice daily, 5 days on/2 days off, for 2 weeks in mouse L-CNV model*****
- ✓ **Efficacy was also seen after single <u>intravitreal</u> injection of 20µM APX3330 in Vldlr $^{-/-}$ mice model******

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Silva et al. ARVO 2021 Annual Meeting
*Published data on EYLEA. This study was performed independently from APX3330 study and is a cross-study comparison.
Li 2014; * Pasha 2018; ****Jiang 2011 (*Vldlr* $^{-/-}$: Very Low-Density Lipoprotein receptor knock-out mice)


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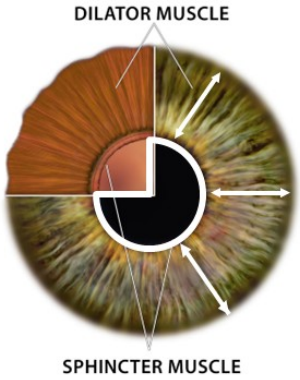
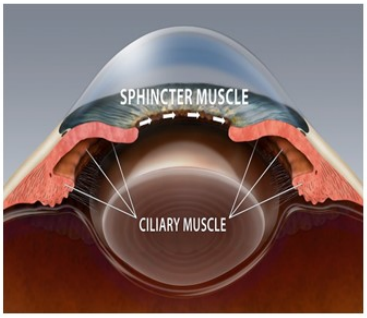
Appendix

Phentolamine Ophthalmic Solution 0.75%'s Differentiated MOA as an Alpha-1 Blocker

No Engagement of Ciliary Muscle, No Headaches and Lower Risk of Retinal Detachment

Phentolamine is the Active Ingredient in POS: a non-selective α Antagonist





Phentolamine blocks α1 receptors on the **Iris Dilator Muscle up to 24 hours**

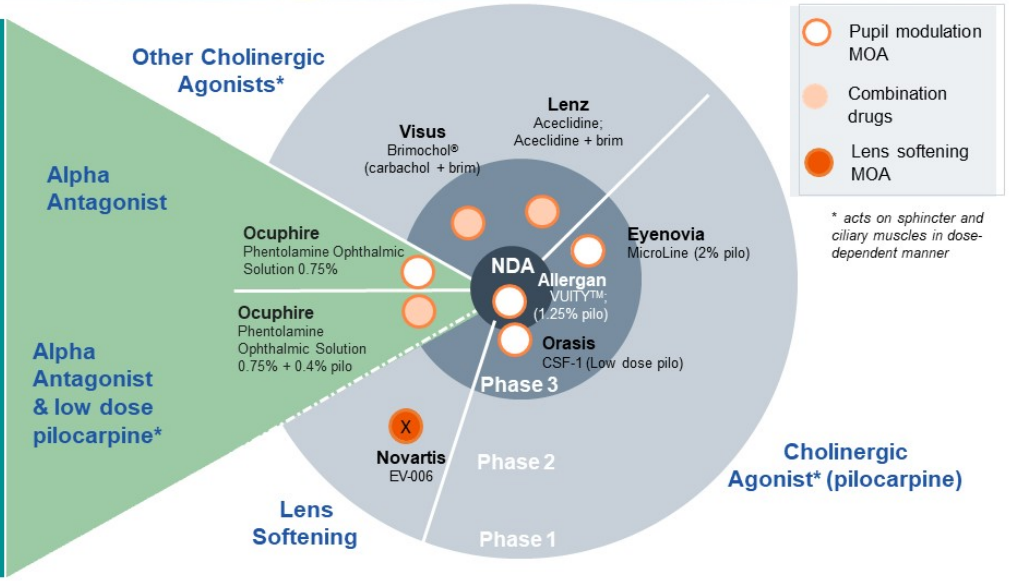
↓

Decreases pupil size (moderately) **without affecting the iris sphincter or ciliary muscles**

505(b)(2) Regulatory Pathway Supported by Prior Phentolamine Approvals in Non-Ophthalmic Indications

A New, Differentiated MOA and Combination Therapy Offers Tunability

- **POS's potential differentiation:**
  1) **New MOA class** (iris dilator muscle inhibitor)
  2) **Favorable safety and tolerability** (e.g.: no headaches, no accommodative spasm, no risk of retinal detachment)
  3) **24-hour durability**
  4) **Broad range of patients including high myopes**
  5) **Improvement in night vision disturbances**
- **POS+LDP may offer added efficacy and tunability**



Corporate Websites as of October 31, 2023.
Grzybowski, A, Markeviciute A, Zemaitiene R. A Review of Pharmacological Presbyopia Treatment. 2020

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Théa let's open our eyes
Shire
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Exhibit 99.2

Ocuphire Pharma Announces Successful End-of-Phase 2 Meeting with FDA for Oral APX3330 in Diabetic Retinopathy

Agreement on Phase 3 Primary Endpoint of 3-step Worsening on Binocular Diabetic Retinopathy Severity Scale (DRSS) Score

Company Plans to Submit a Special Protocol Assessment (SPA)

APX3330 has the Potential to be the First Oral Option for 8M Non-Proliferative Diabetic Retinopathy (NPDR) Patients in the US

FARMINGTON HILLS, Mich., November 2, 2023 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders, today announced the successful outcome of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA), supporting the advancement of oral APX3330 for the treatment of diabetic retinopathy (DR) into Phase 3 studies based on the recently completed Phase 2 ZETA-1 trial.

"We are pleased to have FDA agreement on the primary endpoint for Phase 3 pivotal trials of APX3330 which we believe is the most advanced oral therapy currently in development for diabetic retinopathy," said George Magrath, M.D, MBA., M.S., Chief Executive Officer of Ocuphire. "Results from our Phase 2 ZETA-1 results demonstrate that oral APX3330 has the potential to slow or prevent clinically meaningful progression of diabetic retinopathy, as measured by the percentage of subjects with ≥ 3-step worsening on a binocular diabetic retinopathy severity scale (DRSS), which will be the Phase 3 primary endpoint. As recommended by the FDA, Ocuphire plans to submit a Special Protocol Assessment to agree on the clinical trial protocol and statistical analysis plan for the Phase 3 trials and will share specifics on the study design parameters and anticipated timing once agreed with the FDA. We are grateful for the FDA's support and guidance and look forward to continued collaboration as we advance APX3330 into Phase 3 development."

The EOP2 meeting was supported by results from the previously completed Phase 2 ZETA-1 trial. The randomized, double-masked, placebo-controlled Phase 2 trial was designed to evaluate the efficacy and safety of oral APX3330 in diabetic retinopathy patients. A higher percentage of placebo-treated patients had ≥ 3-step worsening on binocular DRSS from baseline compared to APX3330-treated patients at 24 weeks. APX3330 demonstrated favorable safety and tolerability in diabetic patients.

David Brown, M.D., F.A.C.S., co-chairman of the medical leadership board at Retina Consultants of America (RCA) said, “Given the increasing number of DR patients and current treatment options, I am encouraged by the results of the ZETA-1 trial showing that APX3330 can potentially slow or prevent progression to vision threatening diseases such as Proliferative Diabetic Retinopathy. The current treatment paradigm for NPDR patients is for physicians to monitor progression every 4-6 months depending on DR severity. Approved anti-VEGF therapies are not widely utilized in NPDR patients because of the necessity for consistent intravitreal injections in asymptomatic patients. A safe convenient oral medication that could slow or prevent diabetic retinopathy would be a major advance in our fight against diabetic blindness.”

About APX3330

APX3330 is a first-in-class, small molecule, oral inhibitor of the transcription factor regulator Ref-1 (reduction-oxidation effector factor-1). With a novel dual mechanism of action, APX3330 blocks the downstream pathways regulated by Ref-1 – which involve angiogenesis (VEGF) and inflammation (NFkB) – to decrease abnormal activation of both angiogenesis and inflammatory pathways that are implicated across several ocular diseases, including DR, DME, and age-related macular degeneration (AMD). APX3330 has shown a favorable safety and tolerability profile in 12 clinical trials conducted in healthy, hepatitis, cancer, and diabetic subjects.

About Ocuphire Pharma

Ocuphire Pharma, Inc. is a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders.

Ocuphire’s lead retinal product candidate, APX3330, is a first-in-class small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein). Ref-1 is a regulator of transcription factors such as HIF-1a and NF-kB. Inhibiting REF-1 reduces levels of vascular endothelial growth factor (“VEGF”) and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. Through inhibition of Ref-1, APX3330 normalizes the levels of VEGF to physiologic levels, unlike biologics that deplete VEGF below the levels required for normal function. APX3330 is an oral tablet administered twice per day for the treatment of diabetic retinopathy (“DR”). A Phase 2 study in subjects with DR and an End-of-Phase 2 meeting have recently been completed, and a Special Protocol Assessment is planned to be submitted with the U.S. Food and Drug Administration (FDA).

DR affects approximately 10 million people with diabetes and is projected to impact over 14 million Americans by 2050. DR is classified as Non-Proliferative Diabetic Retinopathy (“NPDR”), the early stage of the disease in which symptoms may be mild or non-existent or Proliferative Diabetic Retinopathy (“PDR”) which is the more advanced stage of diabetic eye disease that can be highly symptomatic with loss of vision. Approximately 80% of DR patients have NPDR that will progress to PDR if left untreated. Despite the risk for visual loss associated with this disease, over 90% of NPDR patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is due to the treatment burden of the frequent eye injections required with currently approved therapies for this disease. APX3330 as an oral tablet has the potential to be an early, non-invasive treatment for the 8 million NPDR patients in the US. Treatment with APX3330 is expected to delay or prevent progression of NPDR, thereby reducing the need for expensive intravitreal injections with anti-VEGF therapies and reducing the likelihood of vision loss due to DR.

Ocuphire has also in-licensed APX2009 and APX2014, which are second-generation analogs of APX3330. The unique dual mechanism of action of these Ref-1 inhibitors of reducing angiogenesis and inflammation could potentially be beneficial in treating other retinal diseases such as age-related macular degeneration, and geographic atrophy. Ocuphire is currently evaluating local delivery routes in addition to the systemic (oral) route as part of its pipeline expansion in retinal therapies.

Ocuphire has a partnership with Viatris, Inc. to develop and commercialize phentolamine ophthalmic solution 0.75%. Phentolamine is a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size by uniquely blocking the alpha-1 receptors found on the iris dilator muscle without affecting the ciliary muscle. In September 2023, the FDA approved RYZUMVI™ (phentolamine ophthalmic solution 0.75%) to treat pharmacologically induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic agents (e.g., tropicamide). Phentolamine ophthalmic solution 0.75% is also in Phase 3 clinical development for the treatment of presbyopia and dim light (night) vision disturbances.

For more information, visit www.ocuphire.com

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning the End-of-Phase 2 meeting with the FDA to confirm Phase 3 registration endpoints, study parameters for Phase 3 pivotal studies, and FDA agreement on Special Protocol Assessment. These forward-looking statements are based upon Ocuphire’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) the effects of COVID-19 on clinical programs and business operations, (ix) risks that the Viatris partnership may not facilitate the commercialization or market acceptance of Ocuphire’s product candidates; (x) the success and timing of commercialization of any of Ocuphire’s product candidates and (xi) the maintenance of Ocuphire’s intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Ocuphire from time to time with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Ocuphire undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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