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): May 10, 2024

Ocuphire Pharma, Inc.

(Exact name of registrant as specified in its charter)

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

37000 Grand River Avenue, Suite 120 **Farmington Hills, MI** (Address of principal executive offices)	**48335** (Zip Code)

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

(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, $0.0001 par value 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

Representatives of Ocuphire Pharma, Inc. (the "***Company***") plan to share the presentation attached hereto as Exhibit 99.1 in upcoming meetings with investors and others.

The information in this Item 7.01 of this Current Report on Form 8-K, and Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Description**
99.1	Presentation (May 2024)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Dated: May 10, 2024

OCUPHIRE PHARMA, INC.

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

Exhibit 99.1

NPDR Subset Analysis of ZETA-1 Phase 2 Trial

A moderate to severe NPDR-qualifying subgroup analysis to inform future clinical trials

Ocuphire PHARMA

NPDR, non-proliferative diabetic retinopathy.

ZETA-1 Phase 2 Study Design and Demographics

- **Primary endpoint:** % of subjects with a **≥ 2 step improvement in monocular ETDRS DRSS** at Week 24
- **Study eye:** DR graded moderately severe to severe NPDR or mild PDR (monocular DRSS 47, 53, or 61)
- **Fellow eye:** No exclusion*

Baseline DRSS Scores		APX3330 (n=51)	Placebo (n=52)
DRSS Score – Study Eye			
47	Moderately severe NPDR	22 (43%)	18 (35%)
53	Severe or very severe NPDR	25 (49%)	28 (54%)
61	Mild PDR	4 (8%)	6 (12%)
DRSS Score – Fellow Eye			
43 or Lower	Mild to moderate NPDR or better	15 (29%)	12 (23%)
47	Moderately severe NPDR	15 (29%)	22 (42%)
53	Severe or very severe NPDR	14 (28%)	11 (21%)
61	Mild PDR	1 (2%)	4 (8%)
65 or Higher	Moderate to severe PDR	4 (8%)	3 (6%)

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

*Two APX3330 subjects did not have available DRSS scores in the fellow eye at screening.
BID, twice-daily; CST, central subfield thickness; DME, diabetic macular edema; DRSS, Diabetic Retinopathy Severity Scale; ETDRS, Early Treatment of Diabetic Retinopathy Study; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.
Source: ZETA-1 Table 14.1.2.1.

ZETA-1 Actual Compared to NPDR Subset

- **"ZETA-1 Actual"** dataset included 97 patients with evaluable DRSS in both eyes at baseline
- **"NPDR Subset"** is a moderate to severe NPDR-qualifying subgroup analysis **to inform future clinical trials:**
  - DRSS Level 43, 47, or 53 in both eyes, with Level 47 or 53 in at least one eye and no CI-DME at baseline
  - Post-hoc analysis of 3 step worsening/improvement on a Binocular DRSS Person-Level Scale, BCVA, and development of PDR

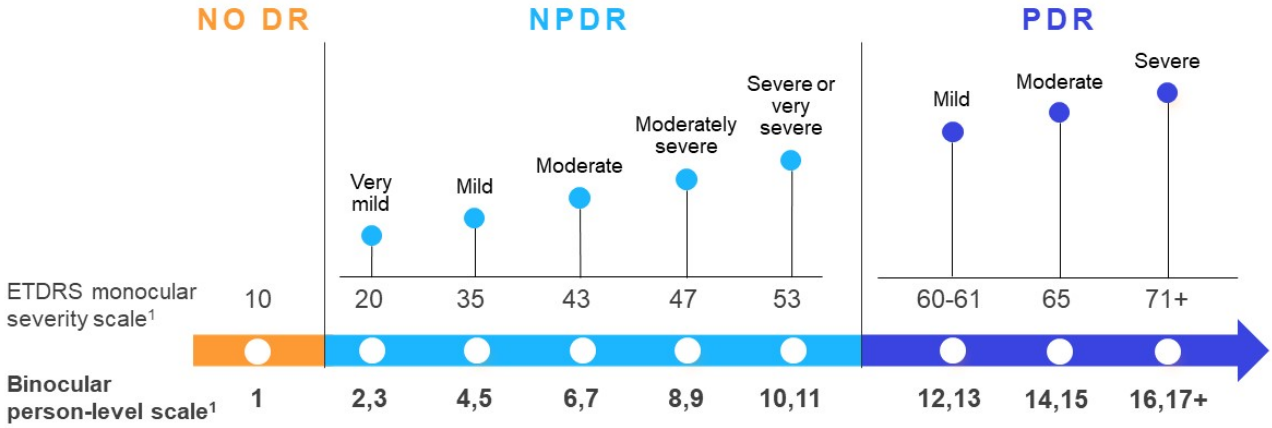
Difference Between Baseline Characteristics for ZETA-1 Actual and NPDR Subset

	ZETA-1 Actual (n)	NPDR Subset (n)
Population with both eyes evaluable for DRSS[1]	**97[1]**	**59**
Subjects with PDR	22	0
Subjects with DME	15	0
Subjects with PDR or DME[2]	35	0
Subjects with one eye better than 43 and no DME	3	0

38 subjects excluded; NPDR Subset includes subjects at high risk for progression to PDR

Source: ZETA-1 Table 16.2.6.1 and Table 16.2.6.2
[1] One subject did not have DRSS evaluation in the fellow eye at baseline
[2] Two subjects had PDR and DME at baseline
BCVA, best-corrected visual acuity; CI-DME, center-involved diabetic macular edema; DME, diabetic macular edema; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.
Statistical validation conducted by Summit Analytical, LLC

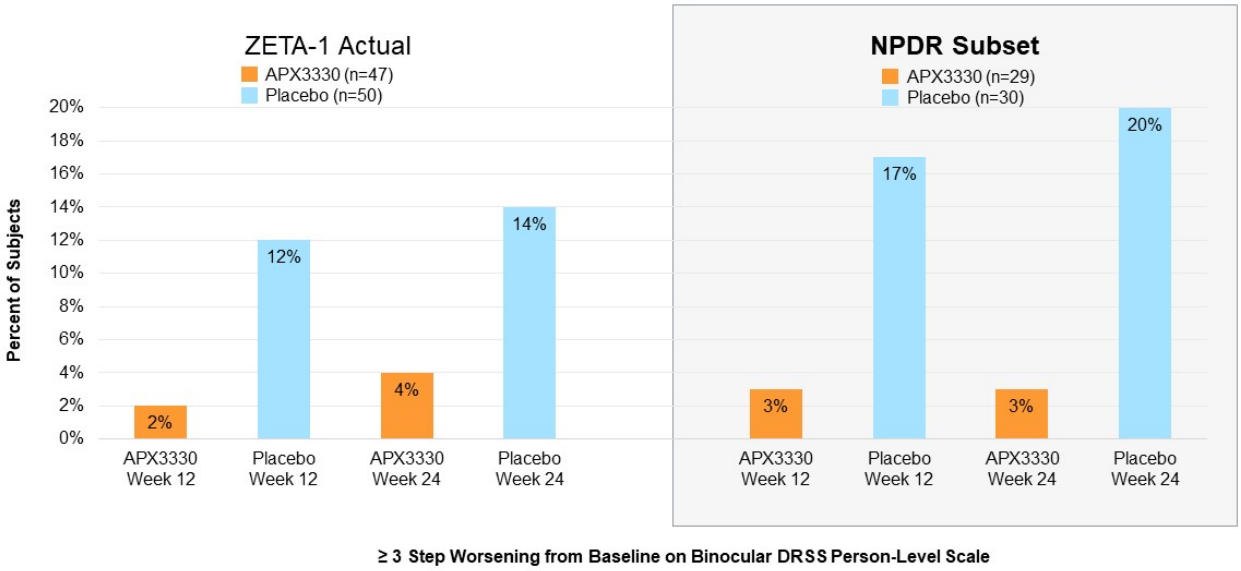
Binocular DRSS is a Validated and Well-Established Scale to Evaluate Systemic Therapies for Diabetic Retinopathy



≥ 3 step worsening on the binocular DRSS is considered clinically meaningful

Patients graded by a central reading center based on fundus photography.
DR, diabetic retinopathy; DRSS, Diabetic Retinopathy Severity Scale; ETDRS, Early Treatment Diabetic Retinopathy Study; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.
1. Chew EY, et al. *N Engl J Med.* 2010;363:233-44.

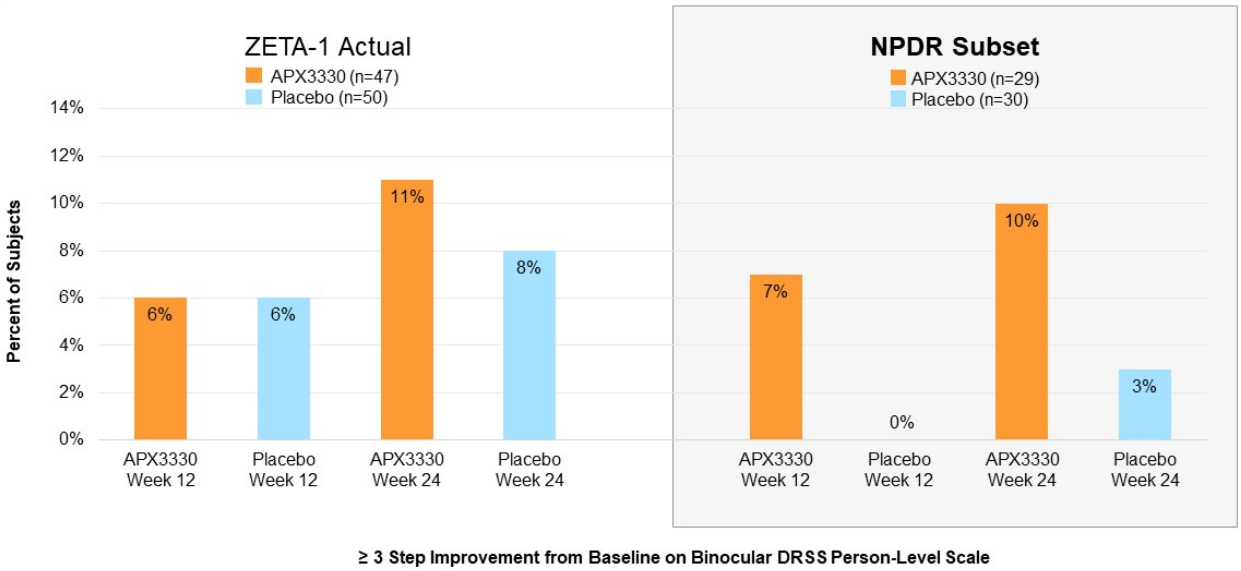
NPDR Subset Amplifies **3 Steps or Greater Worsening** on the Binocular DRSS Person-Level Scale



≥ 3 Step Worsening from Baseline on Binocular DRSS Person-Level Scale

DRSS, Diabetic Retinopathy Severity Scale; NPDR, non-proliferative diabetic retinopathy.
Source: ZETA-1 Table 14.2.2.7.3 and Table 14.2.2.7.6.

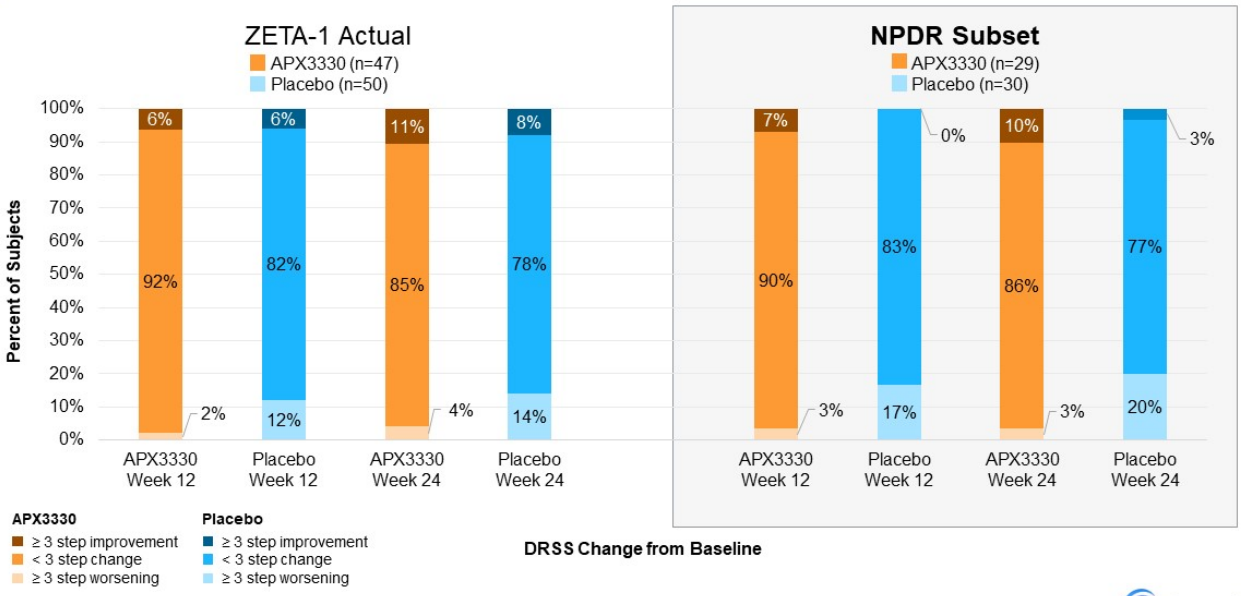
NPDR Subset Amplifies **3 Steps or Greater Improvement** on the Binocular DRSS Person-Level Scale



≥ 3 Step Improvement from Baseline on Binocular DRSS Person-Level Scale

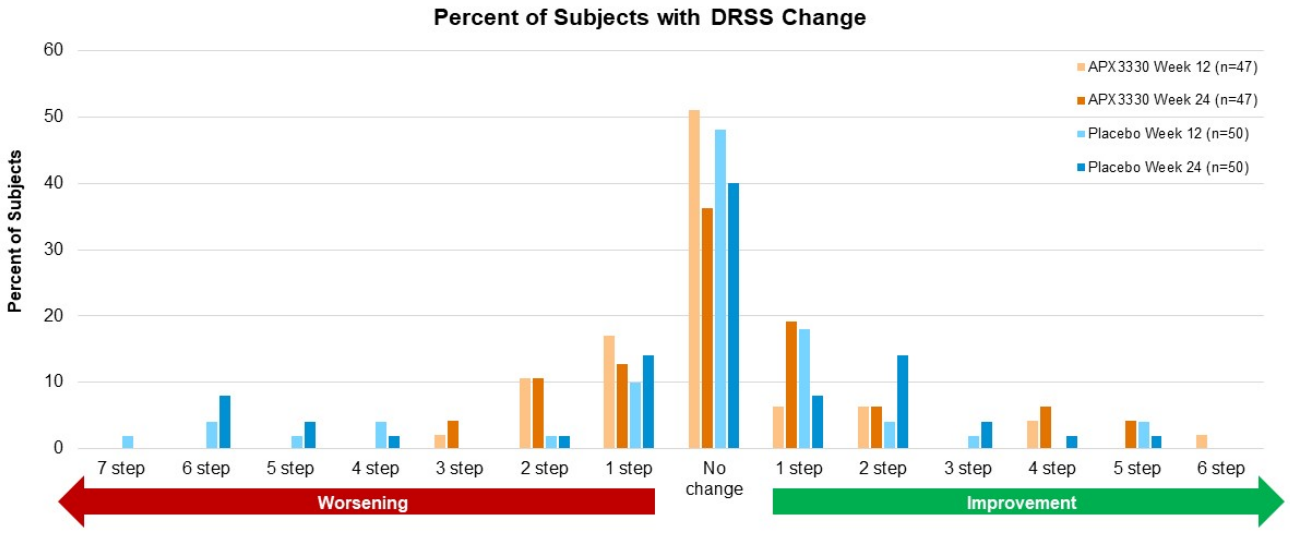
DRSS, Diabetic Retinopathy Severity Scale; NPDR, non-proliferative diabetic retinopathy.
Source: ZETA-1 Table 14.2.2.7.3 and Table 14.2.2.7.6.

NPDR Subset Shows Enhanced Treatment Benefit on the Binocular DRSS Person-Level Scale



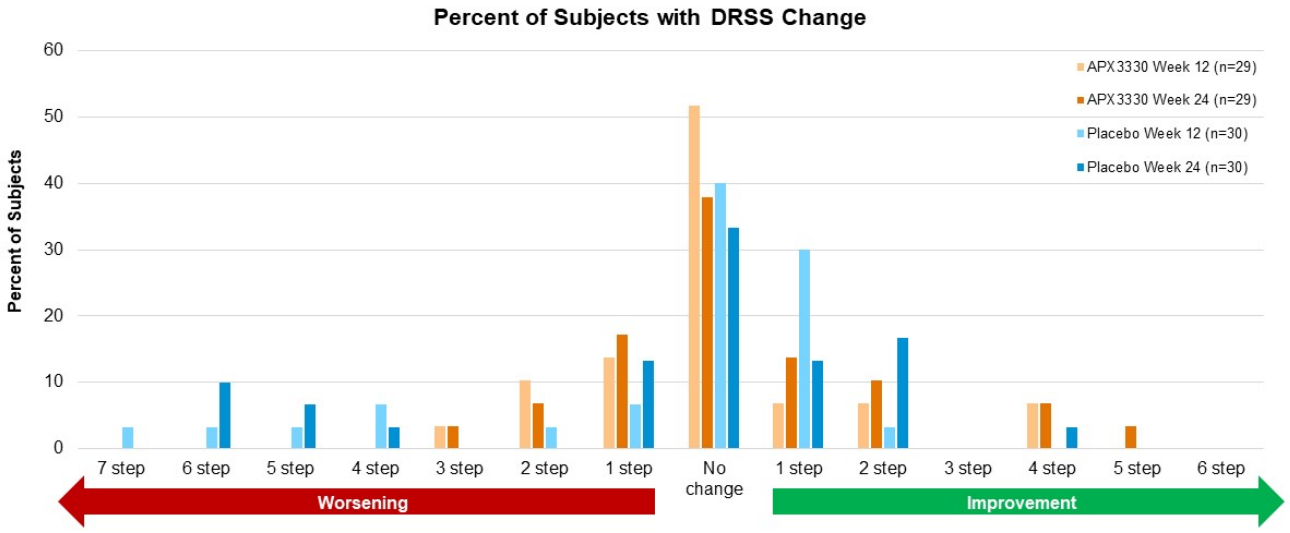
DRSS, Diabetic Retinopathy Severity Scale; NPDR, non-proliferative diabetic retinopathy.
Source: ZETA-1 Table 14.2.2.7.3 and Table 14.2.2.7.6.

ZETA-1 Actual: Fewer APX3330 Subjects Worsened and More Improved Compared to Placebo Subjects



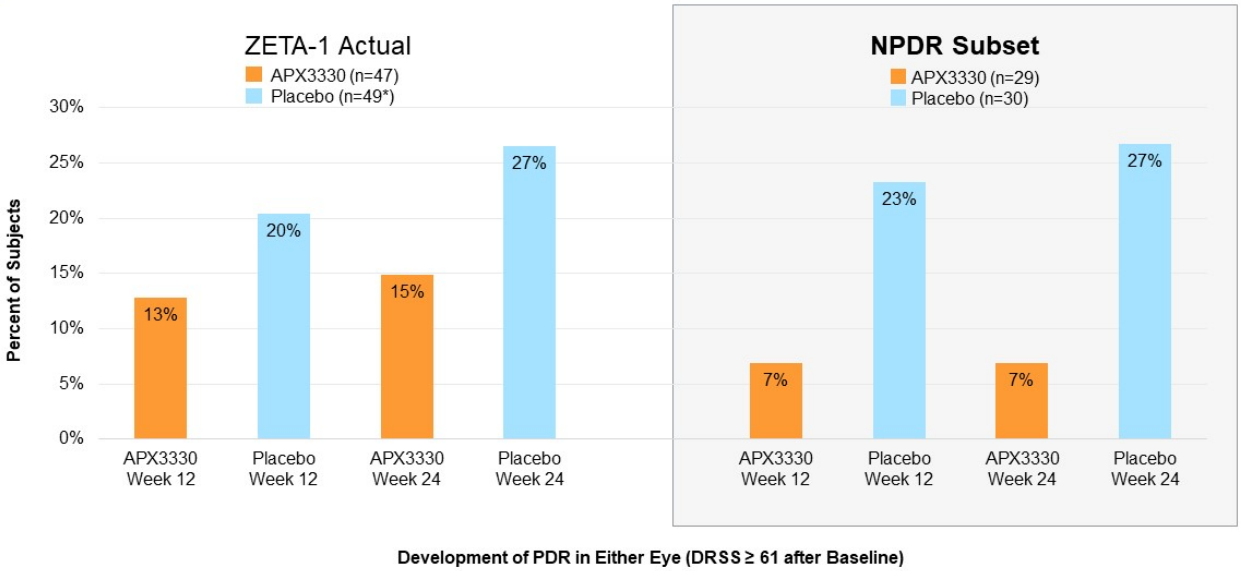
DRSS, Diabetic Retinopathy Severity Scale
Source: ZETA-1 Table 14.2.3.7.1.

NPDR Subset Exhibits Increased Treatment Benefit in Subjects with 3 Steps or Greater Worsening



DRSS, Diabetic Retinopathy Severity Scale.
Source: ZETA-1 Table 14.2.3.7.3.

NPDR Subset Demonstrates Enhanced Treatment Effect with Fewer APX3330 Subjects Developing PDR Compared to Placebo

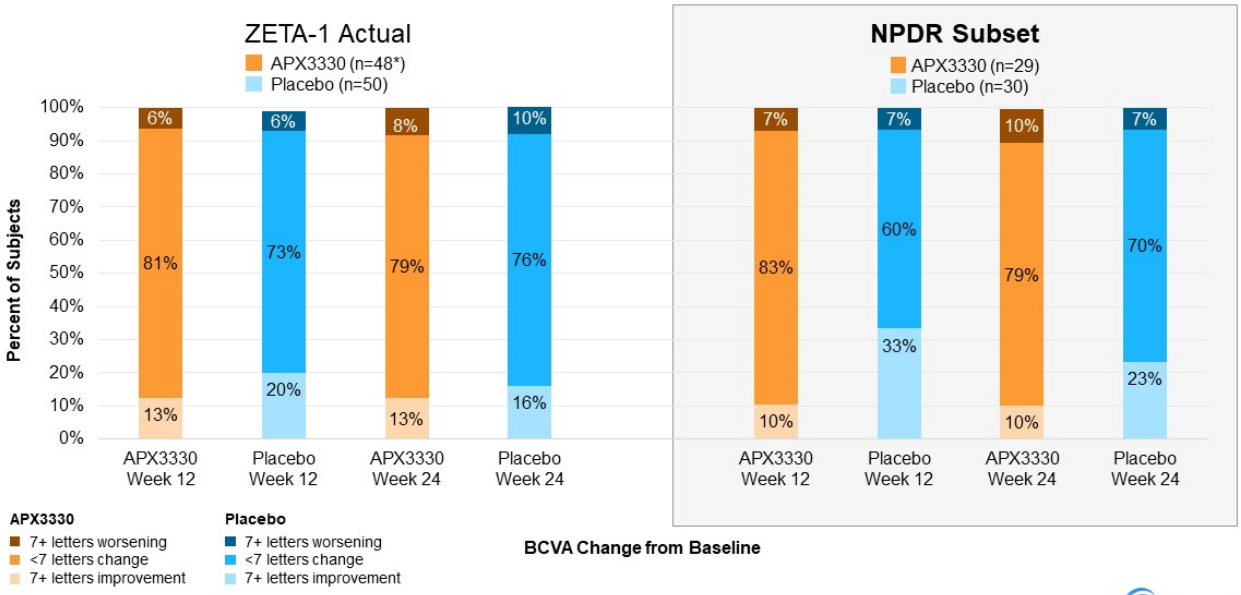


Development of PDR in Either Eye (DRSS ≥ 61 after Baseline)

NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.
*One placebo subject did not have evaluable post-baseline data due to discontinuation of study drug.
Source: ZETA-1 Table 14.2.6.7.3 and Table 14.2.6.7.5.

Ocuphire PHARMA

BCVA Comparable Between Treatment Groups at Week 12 and Week 24



BCVA, best-corrected visual acuity, study eye; NPDR, non-proliferative diabetic retinopathy.
*One APX3330 subject had study eye data only.
Source: ZETA-1 Table 14.3.6.6 and Table 14.3.6.8.

APX3330 was Well-Tolerated in ZETA-1

	Placebo (n=52)	APX3330 (n=51)
Total AEs	120	91
Total treatment-related AEs	14	14
Participants with treatment-related AEs	10 (20%)	10 (19%)
Withdrawals due to treatment-related AEs	1 (2%)	1 (2%)

AEs in >5% of Participants

	All AEs		Treatment-related AEs	
	Placebo (n=52)	APX3330 (n=51)	Placebo (n=52)	APX3330 (N=51)
Ocular AEs				
DME	5 (10%)	2 (4%)	1 (2%)	0
DR	6 (12%)	1 (2%)	1 (2%)	0
Vitreous detachment	3 (6%)	0	0	0
Cataract	1 (2%)	3 (6%)	0	0
Non-ocular AEs				
Pruritus (itching)	1 (2%)	6 (12%)	1 (2%)	3 (6%)
Rash	1 (2%)	3 (6%)	1 (2%)	2 (4%)
COVID-19	5 (10%)	1 (2%)	0	0
SARS CoV-2 test positive	3 (6%)	0	0	0

AE, adverse event; DME, diabetic macular edema, DR, diabetic retinopathy.
Source: ZETA-1 Tables 14.3.1.1, 14.3.1.7, 14.3.1.10, 16.2.7.

- Ocular AEs similar between APX3330 and placebo
- Pruritis and rash were typically mild and self-limited
- Participants with DR continued routine medications to manage comorbid conditions

NPDR Subset Demonstrates Potential Benefit of APX3330 in Patients with High Risk NPDR

- NPDR subset suggests treatment effect on 3 steps or greater worsening on the binocular DRSS person-level scale
  - 3% of APX3330 subjects compared to 20% of placebo subjects had 3 steps or greater worsening at Week 24
- NPDR subset suggests enhanced treatment effect on development of PDR
  - 7% of APX3330 subjects compared to 27% of placebo subjects developed PDR (DRSS ≥ 61 after baseline in either eye) at Week 24
- APX3330 was well-tolerated
- NPDR subset informs planned clinical trial investigating APX3330 in slowing PDR conversion in high risk NPDR patients

DRSS, Diabetic Retinopathy Severity Scale; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.