Ocuphire PHARMA

Restore Vision & Clarity

January 25, 2023

ZETA-1 APX3330 Topline Results

Investor Webcast

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Agenda and Speakers

Topic
ZETA-1 Key Takeaways and APX3330 Oral MOA
ZETA-1 Trial Design and Demographics
ZETA-1 Efficacy Findings
ZETA-1 Safety Findings
Overall Summary and Next Steps
Q&A

Mina Sooch, MBA
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Vitreoretinal Specialist

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APX Scientific Founder and Medical Advisor

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ZETA-1 Key Takeaways and APX3330 Oral MOA

ZETA-1 Trial: Key Takeaways

- APX3330 achieved statistical significance on a key pre-specified secondary endpoint of preventing clinically meaningful progression of diabetic retinopathy (as defined by binocular 3 or more steps worsening on the DRSS[1]) after 24 weeks of treatment
  - Trend toward more efficacy at 24 weeks vs 12 weeks, suggests that the 52-week Phase 3 trial may generate a larger signal due to an increase in % of placebo subjects who progress
- Prevention of 3-step worsening (binocular) is a suitable endpoint for an oral, systemically drug ➔ Ocuphire plans to go forward with this potential registration endpoint in Phase 3 following confirmation with the FDA in EOP2 meeting
- Oral APX3330 demonstrated favorable safety and tolerability
- Retinal KOLs feedback suggest that slowing of DR progression with an oral agent would be a useful treatment in patients with background DR and good visual function
- If approved, APX3330 could be an important new primary preventative therapeutic option that could be used in a large number of diabetic patients who are earlier in their disease

1. diabetic retinopathy severity score
Source: ZETA-1 Clinical Trial

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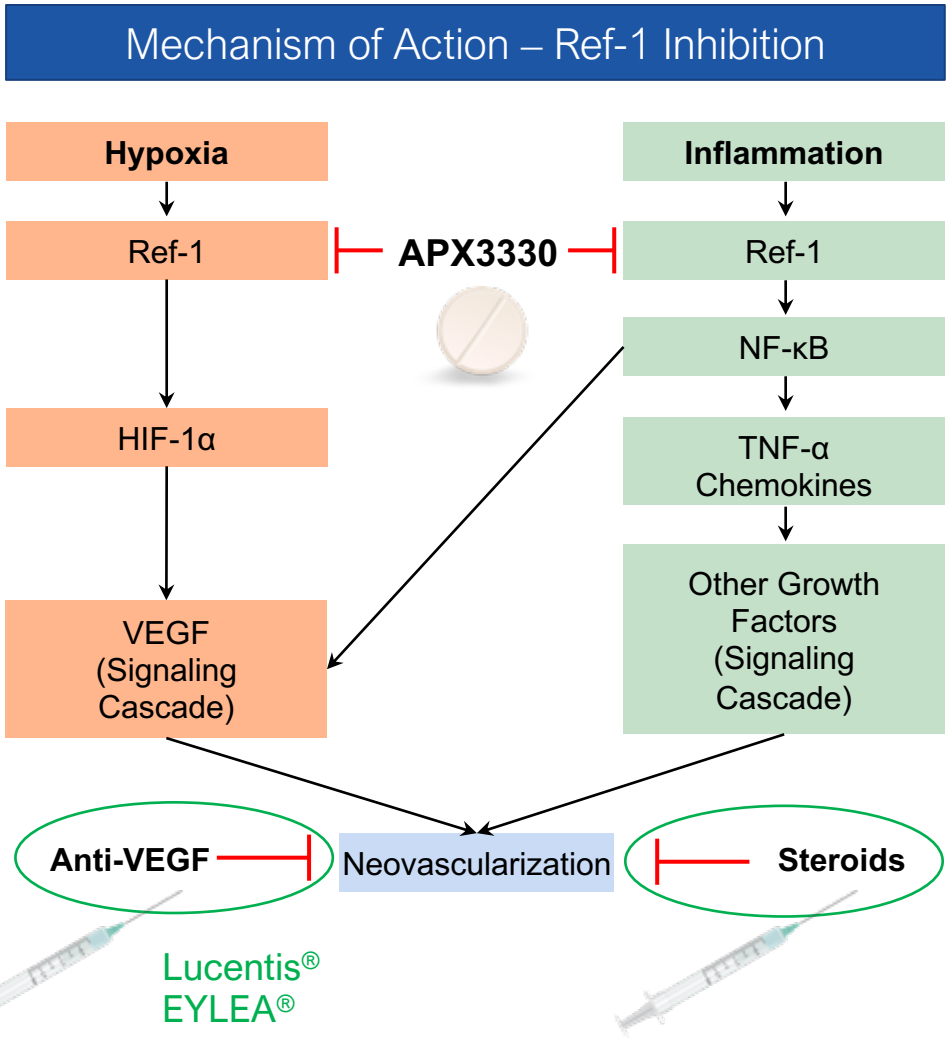
APX3330 History and Ref-1 Inhibition Mechanism

Ref-1 Involved in Multiple Key Pathways that Contribute to Diabetic Retinopathy and DME



- Ref-1 (reduction-oxidation effector factor-1) is a novel target discovered by Dr. Mark R. Kelley at Indiana University School of Medicine and Ocuphire's Scientific Advisor for APX program
- APX3330 is a small molecule oral drug candidate and a first-in-class inhibitor of Ref-1
- APX3330 previously developed by Eisai for multiple hepatic inflammatory indications and later by Apexian for advanced solid tumors in **11 Phase 1 and 2 trials**
  - Similar oncology origin as approved anti-VEGFs
- **MOA uniquely decreases both abnormal angiogenesis and inflammation by blocking pathways downstream of Ref-1**
- Extensively studied in over **20 in-vitro and animal studies** with favorable efficacy and safety

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

ZETA-1 Trial Design and Demographics

DR/DME ZETA-1 Phase 2 Design

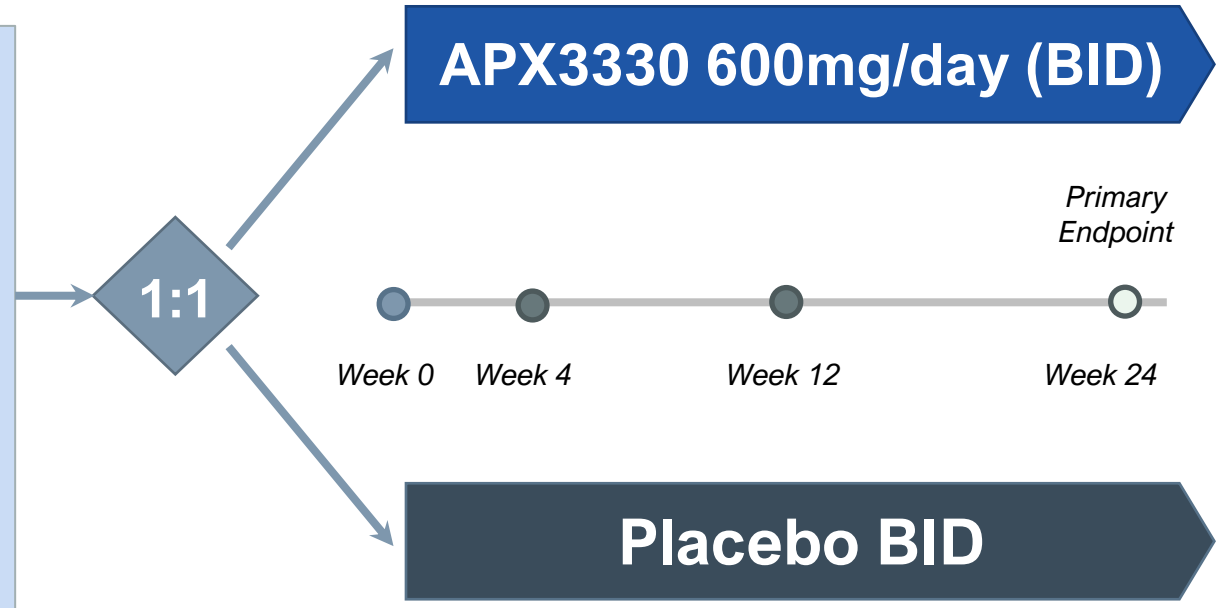
Randomized, Double-Masked, Placebo-Controlled 24-Week Trial (Similar To Eylea P3 DR Trial)

ZETA-1

25 US sites

90-100 participants with moderately severe-to-severe NPDR or mild PDR

Noncentral DME is permitted in study eye and central DME allowed in fellow eye



Eligibility Screening

Randomization

NPDR = non-proliferative diabetic retinopathy
PDR = proliferative diabetic retinopathy

103 Subjects Enrolled (FPFV Apr 2021- LPLV Aug 2022)
Top Line Announced in Early 2023

Endpoints

Primary: % subjects with ≥ 2 step improvement on DRSS (Diabetic Retinopathy Severity Scale) at wk 24

Secondary:

- DRSS worsening*
- DRSS improvement*
- Progression to vision threatening complications
- Central subfield thickness (CST)
- Best Corrected Distance Visual Acuity (BCDVA)
- Rescue subjects
- DME fellow eye status
- Safety and tolerability

Exploratory:

- Labs / PK

**Potential Phase 3 approvable endpoints*

NPDR = non-proliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy
ZETA-1 Clinical Trial is Sponsored by Ocuphire Pharma

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Key Eligibility Criteria in ZETA-1

Oral Medication Provides Binocular Treatment; DME Allowed in Fellow Eye

Inclusion	Exclusion
• Males or non-pregnant females ≥ 18 years of age • At least one eye with DR **DRSS 47, 53, or 61, confirmed by a central reading center)** in which PRP and intravitreal injections of an anti-VEGF agent can be safely deferred for ≥ 6 months in the opinion of the Investigator • **BCVA assessed by ETDRS protocol letters score of ≥ 60 letters (Snellen equivalent 20/63 or better) in the study eye** • Body mass index (BMI) between 18 and 40 kg/m^2, inclusive	• Retinopathy from causes other than diabetes in study eye • Presence of **center involved diabetic macular edema (DME) defined as a central subfield thickness (CST) ≥ 320 µm on SD-OCT** – **Center involved DME in the fellow eye is allowed** • Prior treatment in study eye with focal/grid laser photocoagulation within the past year, PRP at any time, **systemic or intravitreal anti-VEGF agents within last 6 months in study eye** • Intraocular steroids including triamcinolone and dexamethasone implant within the last 6 months • Fluocinolone implant within the last 3 years • HbA1c ≥ 12.0% • Clinically significant systemic disease (e.g., uncontrolled diabetes, myasthenia gravis, cancer, hepatic, renal, endocrine, or cardio-vascular disorders) that might interfere as deemed by Investigator

Source: ZETA-1 Clinical trial

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ZETA-1: Demographics

Well-Balanced Across Arms

	APX3330 n=51	Placebo n=52	Total n=103
Demographics			
Age (years): Mean (Range)	54.3 (26-81)	58.3 (24-78)	56.3 (24-81)
Sex: Male n (%) **Female** n (%)	24 (47%) 27 (53%)	26 (50%) 26 (50%)	50 (49%) 53 (52%)
Race: White n (%) **African American** n (%) **Asian** n (%) **Other** n (%)	40 (78%) 5 (10%) 3 (6%) 3 (6%)	41 (79%) 6 (12%) 1 (2%) 0 (0%)	81 (79%) 11 (11%) 4 (4%) 3 (3%)
Ethnicity: Hispanic or Latino *n (%)* ***Not Hispanic or Latino*** *n (%)*	28 (55%) 23 (45%)	23 (44%) 29 (56%)	51 (50%) 52 (51%)
Time (Years) Since Onset of Diabetes: Mean	15	16	16

Source: ZETA-1 Clinical Trial

ZETA-1: Baseline DRSS Scores Study and Fellow Eye

Well-Balanced Across Arms

	APX3330 n=51	Placebo n=52	Total n=103
DRSS Score – Study Eye			
DRSS Category (Screening) Study Eye [n (%)]			
47 (Moderately severe to severe NPDR)	22 (43%)	18 (35%)	40 (39%)
53 (Moderately severe to severe NPDR)	25 (49%)	28 (54%)	53 (52%)
61 (Mild proliferative diabetic retinopathy)	4 (8%)	6 (12%)	10 (10%)

	APX3330 n=45	Placebo n=49	Total n=94
DRSS Score – Fellow Eye			
DRSS Category (Screening) Fellow Eye [n (%)]			
43 or Lower (Mild to moderate NDPR or better)	**14 (31%)**	**12 (24%)**	**26 (28%)**
47 (Moderately severe to severe NPDR)	13 (29%)	19 (39%)	32 (34%)
53 (Moderately severe to severe NPDR)	12 (27%)	9 (19%)	21 (22%)
61 (Mild proliferative diabetic retinopathy)	1 (2%)	4 (8%)	5 (5%)
65 or Higher (Moderate to severe prolif. DR)	**5 (11%)**	**5 (10%)**	**10 (11%)**

Source: ZETA-1 Clinical Trial

ZETA-1: Baseline Characteristics Study and Fellow Eye

Well-Balanced Across Arms

	APX3330 n=51	Placebo n=52	Total n=103
Baseline Characteristic			
BCVA letters in Study Eye Letters Read (mean)	**81**	**78**	**80 (20/25 Snellen)**
BCVA letters in Fellow Eye *Letters Read (mean)*	76	77	77 *(20/32 Snellen)*
OCT Central Subfield Thickness in Study Eye (µm)	**270**	**271**	**271**
OCT Central Subfield Thickness in Fellow Eye (µm)	292	286	289
Intraocular Pressure in Study Eye (mmHg)	15	16	15
Systolic Blood Pressure (mmHg) (mean)	136	139	138
Diastolic Blood Pressure (mmHg) (mean)	82	80	81
Heart Rate (beats/min) (mean)	78	76	77
Hemoglobin A1C (%) (mean)	8.4	8.3	8.3
Body Mass Index (kg/m^2) (mean)	31	31	31

Good Visual Acuity

Fluid Below DME Definition of 320 micron (µm)

Note: Blood markers are normal range as baselines

Source: ZETA-1 Clinical Trial

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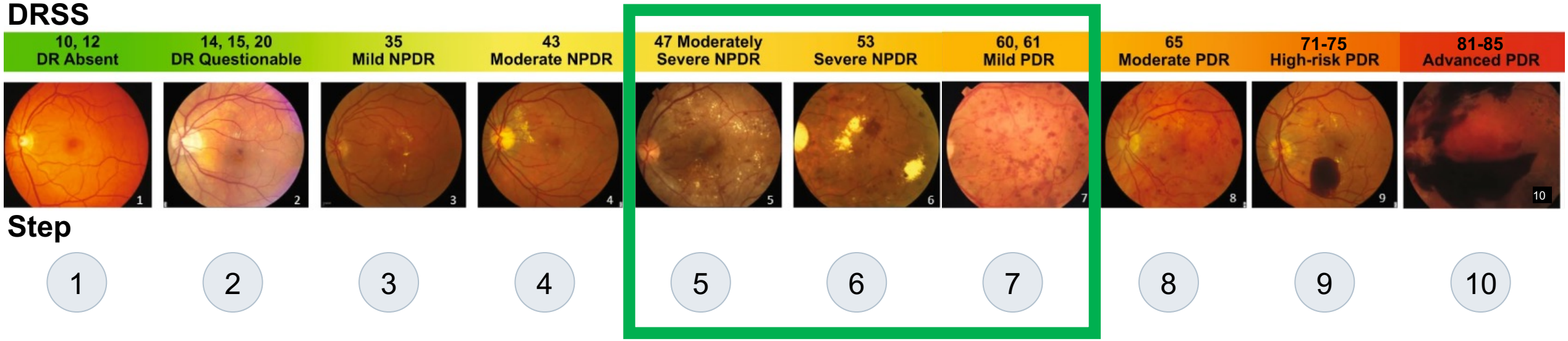
ZETA-1 Efficacy Findings

Background on DRSS Assessment & Binocular DRSS

Diabetic Retinopathy Severity Scale (DRSS)



Monocular calculation: Change in DRSS Step in a Single Eye (Study Eye or Fellow Eye)

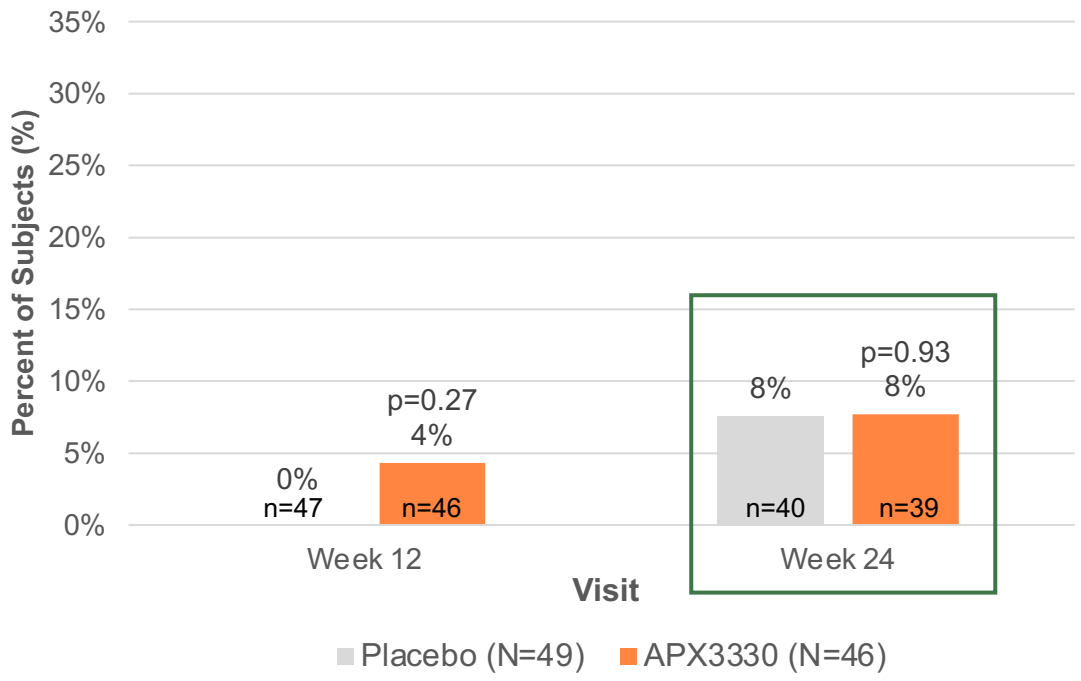
Binocular calculation: Composite Change in DRSS Step in Study Eye and Change in DRSS Step in Fellow Eye

The ETDRS diabetic retinopathy severity scale (DRSS) is a categorical tool for clinical trials that contains 10 discreet steps from no retinopathy to severe proliferative retinopathy derived from the grading of fundus photographs for each eye at a central reading center. Each patients' study eye had a baseline DRSS step of 5, 6 or 7 to be included in this trial.

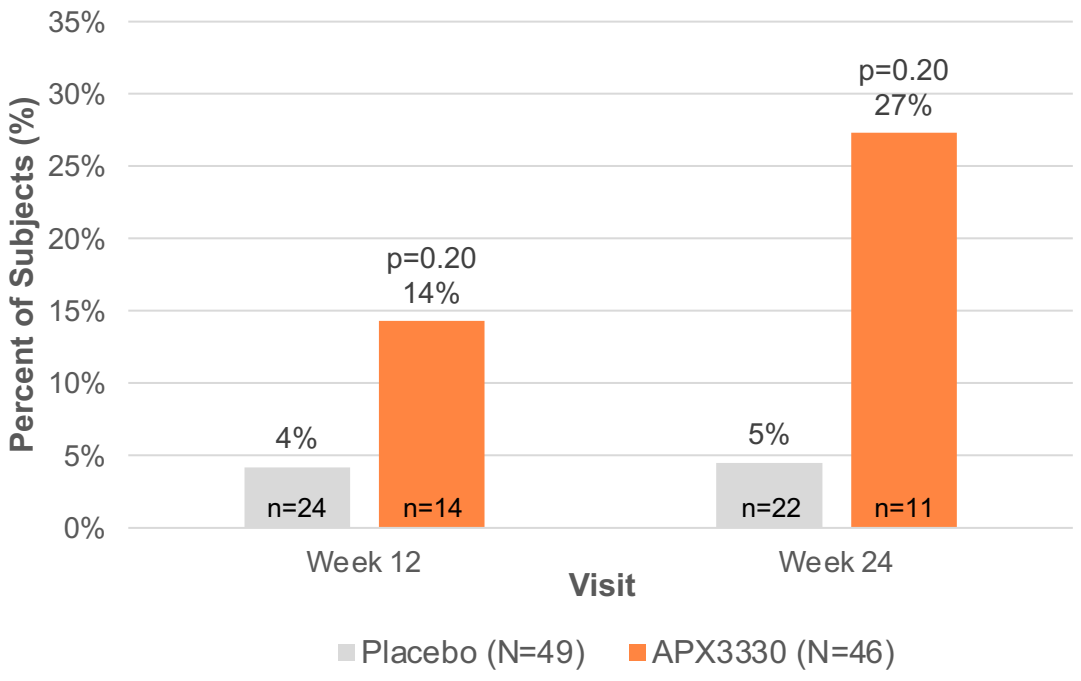
Percent of Subjects With ≥ 2-Step Improvement in DRSS From Baseline

ZETA-1 Did Not Meet the Week 24 Phase 2 Primary Endpoint (based on Anti-VEGF Precedence for DR)

Percent of Subjects With ≥ 2-step Improvement in DRSS From Baseline by Visit (mITT) – **Study Eye**



Percent of Subjects With ≥ 2-step Improvement in DRSS From Baseline by Visit (mITT) – **Qualified Fellow Eye**



Source: ZETA-1 Clinical Trial

Note: Large "N" indicates total number of participants within each arm for the mITT population. Small "n" indicates total number of evaluable eyes for each respective endpoint and arm.

Note: Images from Central Reading Center will be reviewed prior to EOP2 FDA meeting

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Clinically Meaningful Registration Endpoints in DR

Path Forward to Phase 3: Systemic Drugs Should Evaluate DRSS Change in Both Eyes

In retina, opportunity for approval to show **improvement OR worsening (prevention of progression)***

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

- ≥ 2-step DRSS improvement in study eye
  - Eylea (Panorama trial)
  - Lucentis (Rise/Ride trials)

Oral/systemic drugs are different than anti-VEFG IVT as they treat both eyes

Therefore, a suitable evaluation is change in both eyes (binocular)

Potential approvable endpoints for systemic drug in DR (to be confirmed at the EOP2 FDA meeting) include:

- ≥ 3-step binocular DRSS improvement
- **≥ 3-step binocular DRSS worsening**

ZETA-1 Phase 2 trial for APX3330 evaluated key secondary endpoints ≥ 3-step binocular DRSS improvement and worsening to inform design of the Phase 3 registration trial

*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.

Source: ZETA-1 Clinical trial

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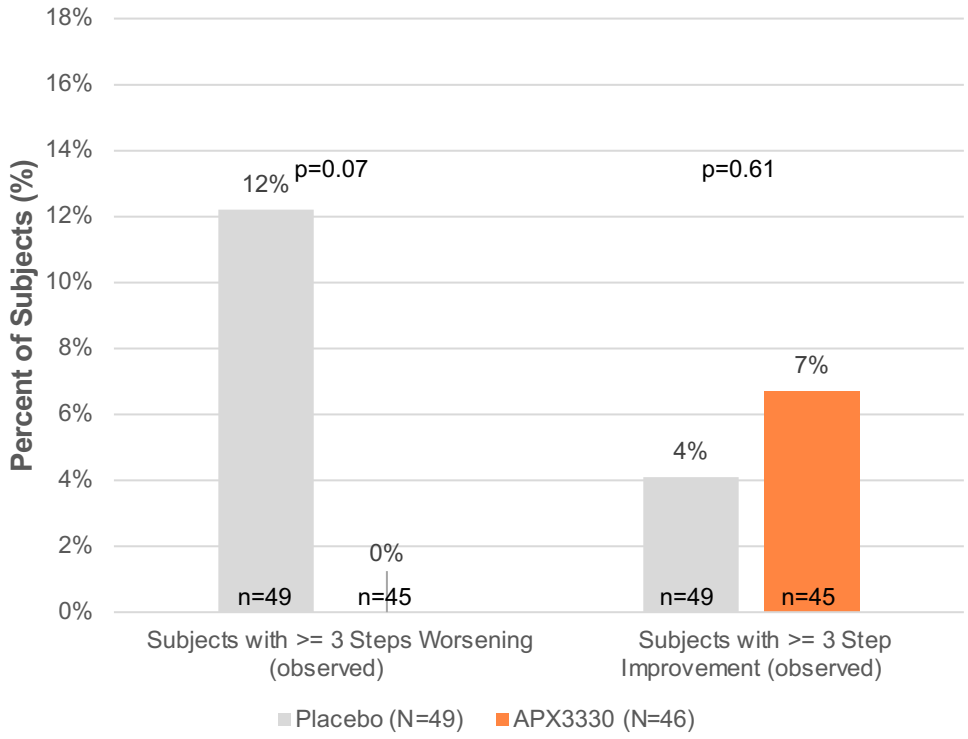
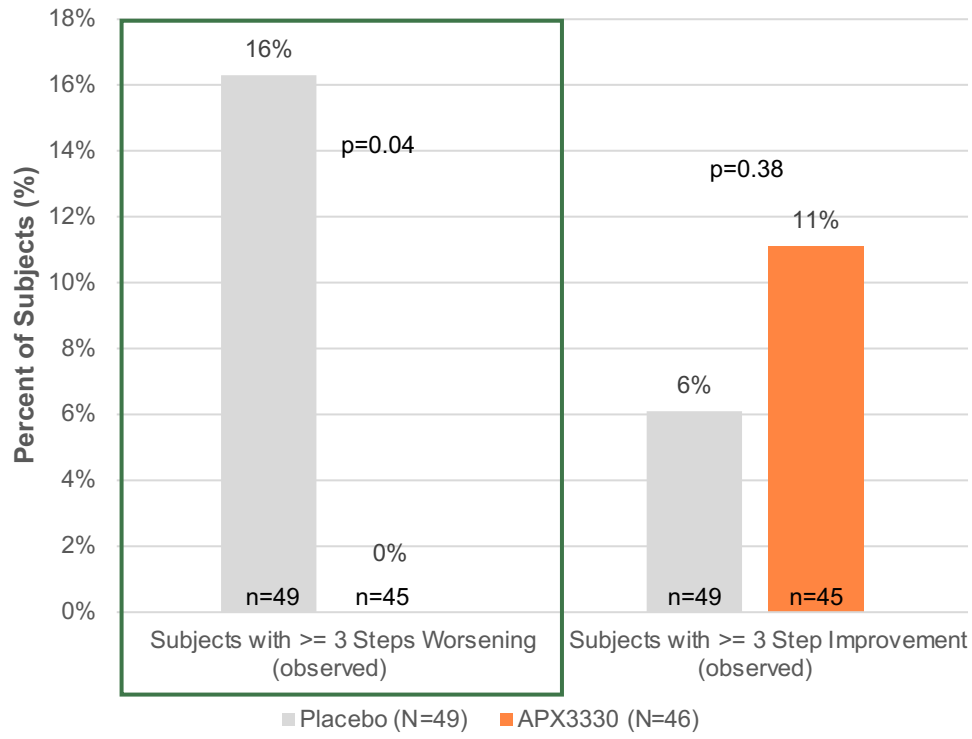
Percent of Subjects With Improv. or Worsening in Binocular DRSS of ≥ 3-Steps

Potential Phase 3 Endpoints as an Oral Drug; Results Improve with Time

Percent of Subjects With Improvement or Worsening in DRSS of ≥ 3 Steps From Baseline Binocular Eyes (mITT-LOCF) - **Week 12**



Percent of Subjects With Improvement or Worsening in DRSS of ≥ 3 Steps From Baseline Binocular Eyes (mITT-LOCF) - **Week 24**



Source: ZETA-1 Clinical Trial

Note: Large "N" indicates total number of participants within each arm for the mITT-LOCF population. Small "n" indicates total number of evaluable eyes for each respective endpoint and arm.

Note: Images from Central Reading Center will be reviewed prior to EOP2 FDA meeting

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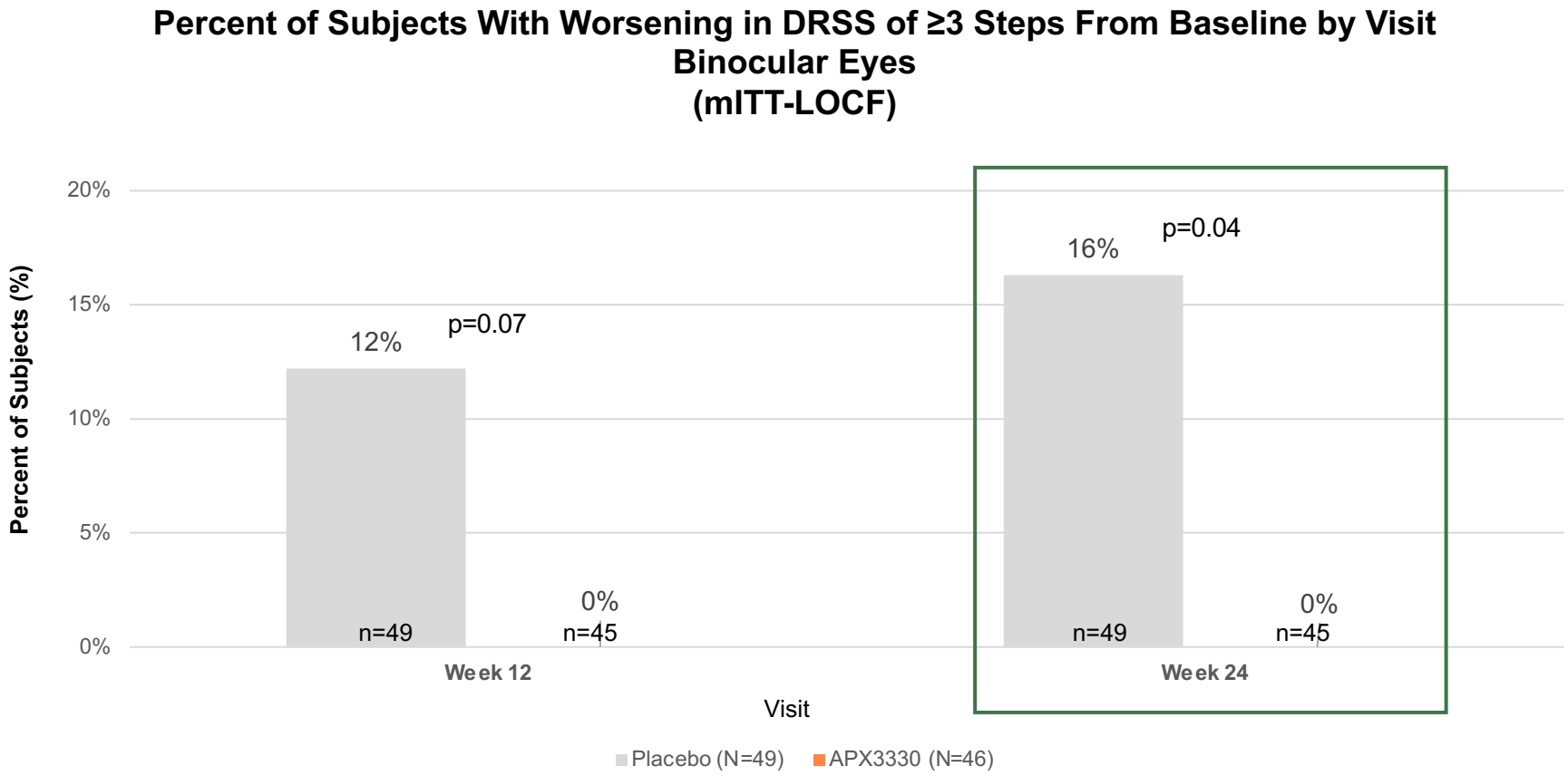
Percent of Subjects With Binocular Worsening in DRSS of ≥ 3-Step

Selected Primary Registration Endpoint for Phase 3, To Be Formally Confirmed at EOP2 FDA Meeting

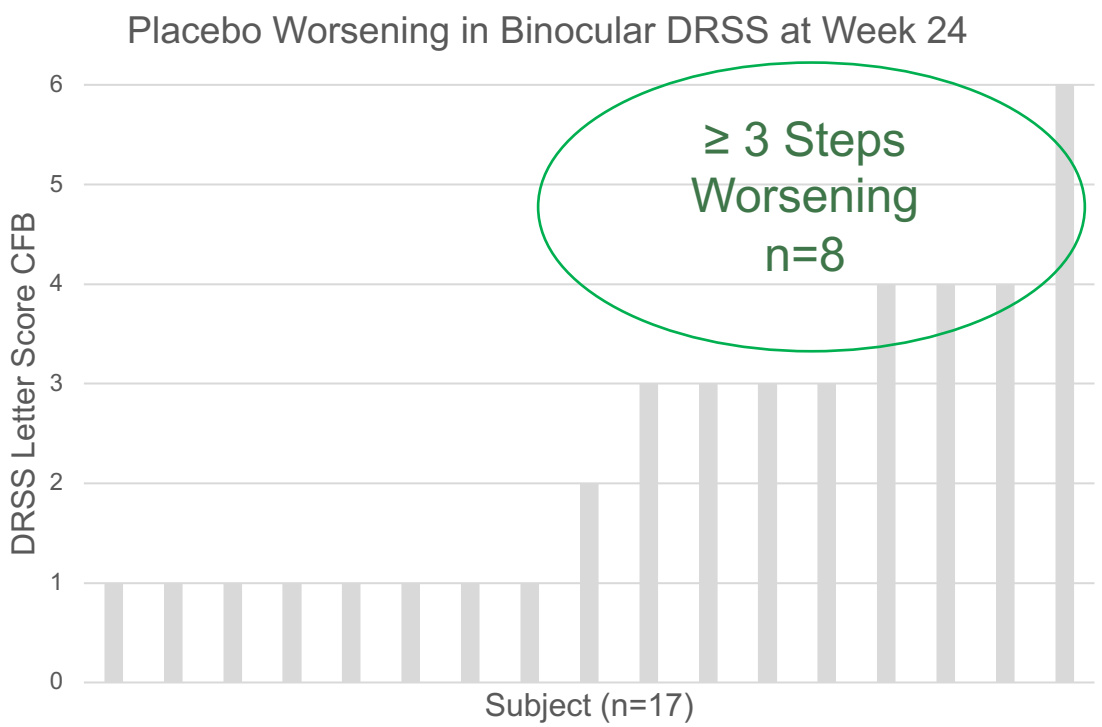


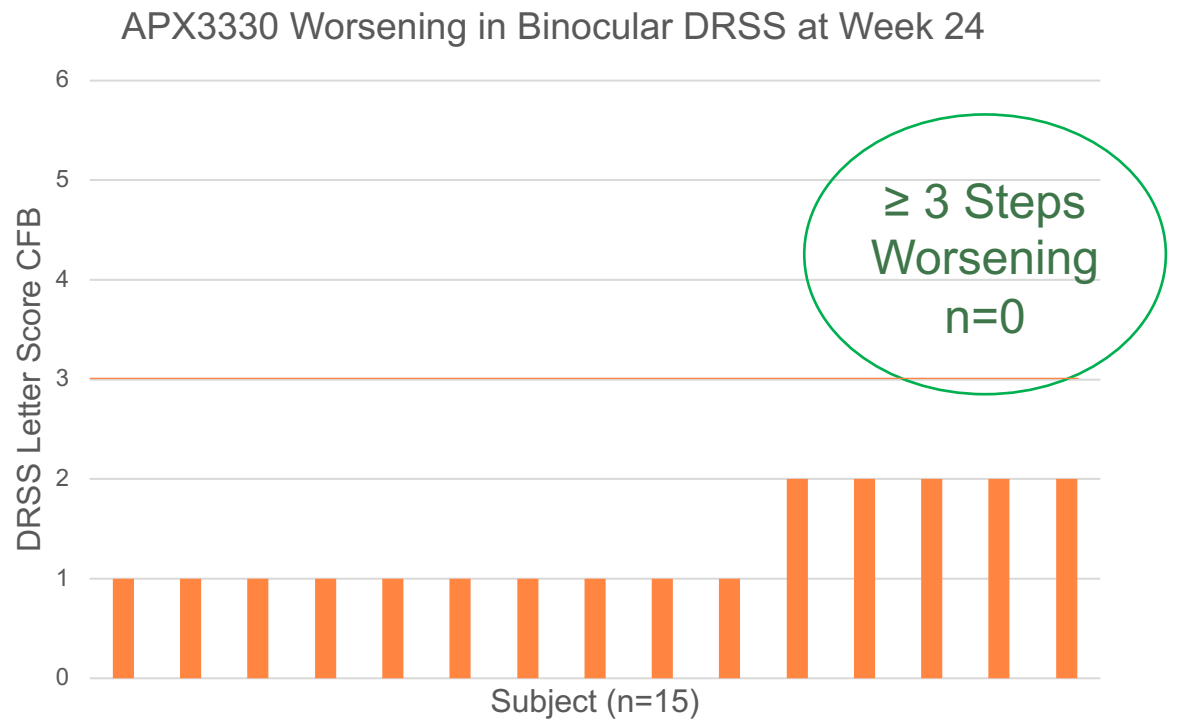
Based on extrapolation from ZETA-1, ~25% of patients may progress by ≥ 3 steps in binocular DRSS over 1 year if untreated

Source: ZETA-1 Clinical Trial
Note: Images from Central Reading Center will be reviewed prior to EOP2 FDA meeting
Note: Large "N" indicates total number of participants within each arm for the mITT-LOCF population. Small "n" indicates total number of evaluable eyes for each respective endpoint and arm

Waterfall by Subject Binocular Change in DRSS at Week 24

8 Subjects in Placebo and 0 in APX3330 had a 3-Step DRSS Worsening at Week 24





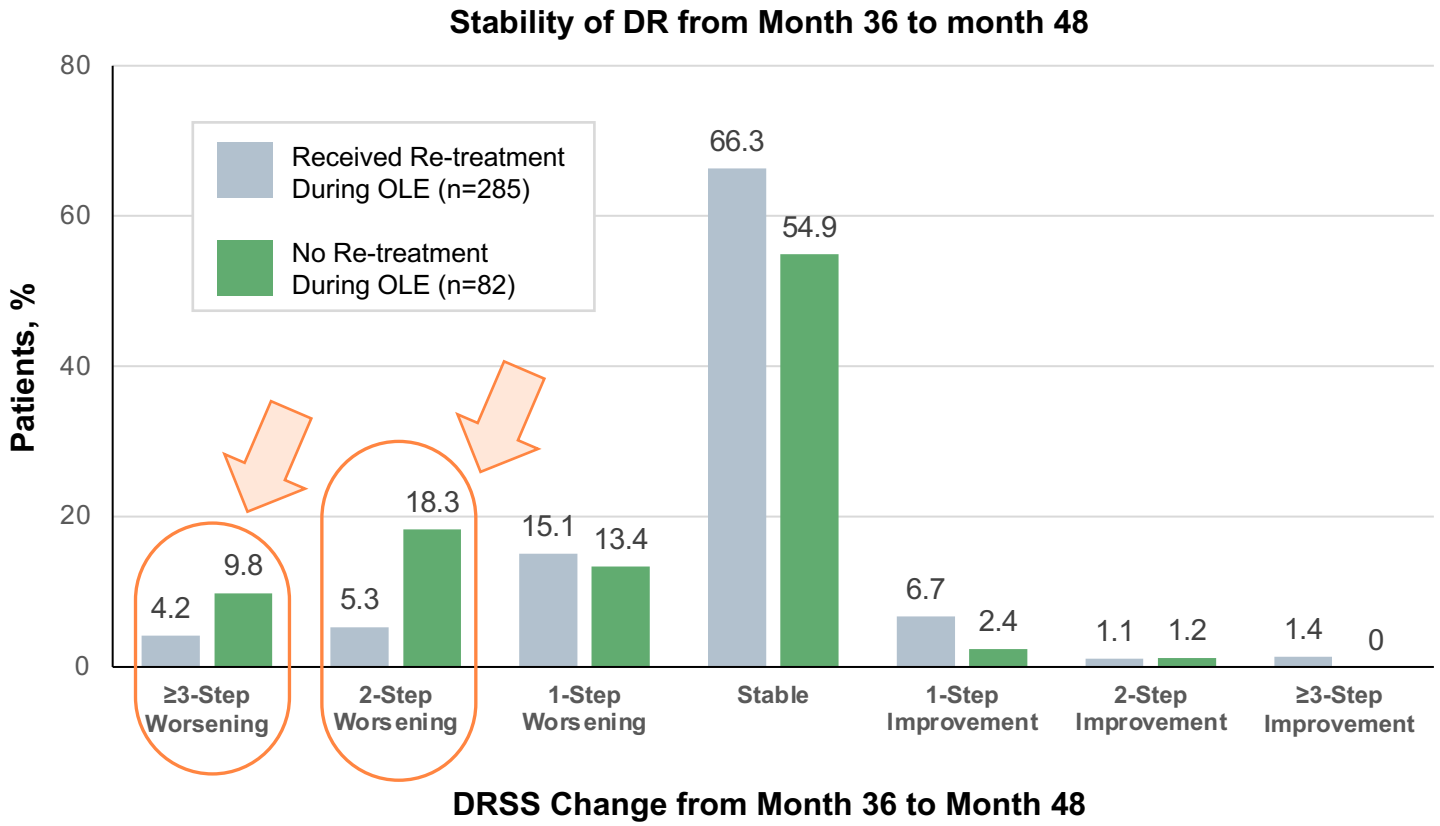
Waterfall plots show subjects with worsening

Source: ZETA-1 Clinical Trial
Note: Images from Central Reading Center will be reviewed prior to EOP2 FDA meeting

Historic Data for Diabetic Patients on DR Progression

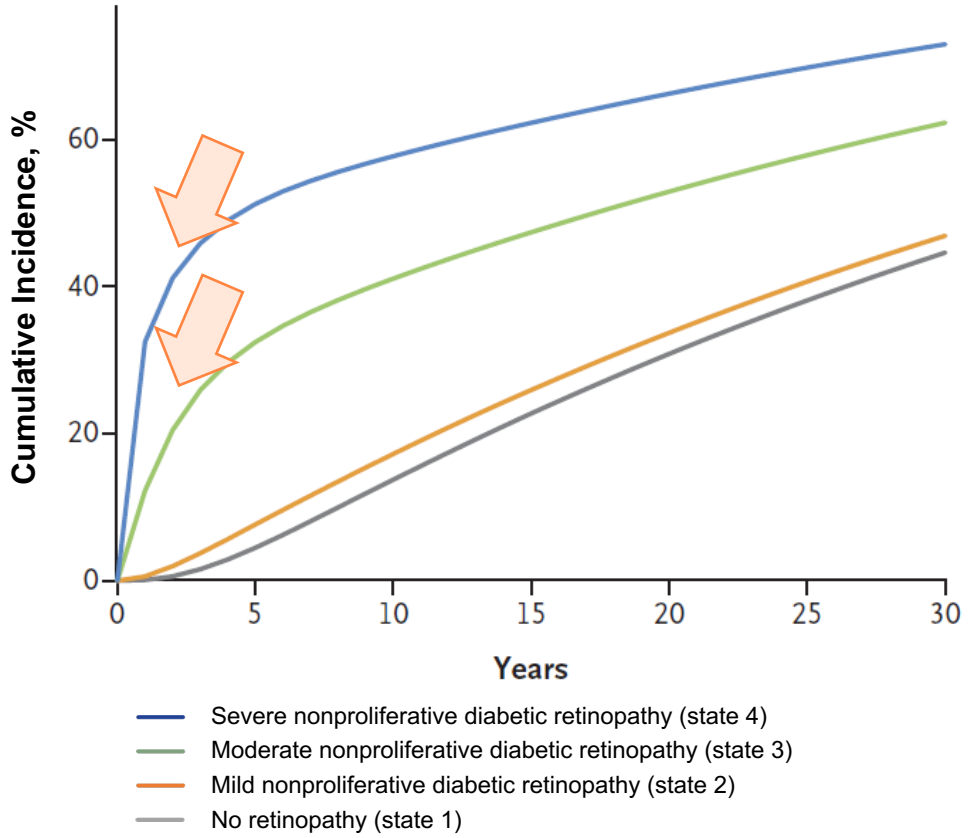
The Worse the DRSS, the Higher the Risk of Vision Threatening Complications

Lucentis data shows that 28% untreated eyes will worsen DRSS by ≥ 2-steps over 1 year



Source – Sun JK, Evidence for Diabetic Retinopathy Progression and Regression from Clinical Trials. Presented at NDI/FDA DR Clinical Trials Design and Endpoints Workshop, June 26, 2015.

Probability of developing PDR or DME is greater with higher baseline NPDR severity



Source - Frequency of Evidence-Based Screening for Retinopathy in Type 1 Diabetes. N Engl J Med. 2017 Apr 20;376(16):1507-1516. doi: 10.1056/NEJMoa1612836. PMID: 28423305; PMCID: PMC5557280

ZETA-1 Safety Findings

PK/Safety Data Findings

Favorable Safety Data for Oral APX3330

- APX3330 PK/serum levels as predicted at 600 mg/day
  - Serum levels of APX3330 are consistent with previous findings in hepatitis and oncology trials
- Fewer subjects lost 5 or more letters at week 24 with APX3330 compared to placebo
- Limited treatment related AEs (mostly mild and transient)
  - Only rash (6% APX3330 vs 2% placebo) and pruritus (12% APX3330 vs 2% placebo) were seen more frequently in APX3330 than placebo
- No treatment related serious TEAES
- No effect on vital signs (BP, HR)
- No effect on physical exam
- No change in liver, kidney, or heart functions
- No effect on IOP
- No effect on clinical labs

Treatment Emergent Adverse Events

APX3330 Safety Similar To or Better Than Placebo

103
Subjects Enrolled

91
Subjects completed thru week 24

211 Treatment Emergent AEs (64 Subjects)
91 (29 Subjects) APX3330, 120 (35 Subjects) Placebo

31
Treatment-Related AEs (in 21 Subjects)

APX3330
14 AEs in 10 subjects
(10 mild, 4 moderate, 0 severe)

Placebo
17 AEs in 11 subjects
(8 mild, 9 moderate, 0 severe)

4
withdrew due to an AE
2 APX, 2 PBO

5
lost to follow-up
2 APX, 3 PBO

3
withdrew consent or site closure
2 APX, 1 PBO

0
Treatment-Related AEs involving liver, heart, kidney, brain, lung, or vital signs

14 SAEs (in 11 Subjects)

3 unrelated SAEs in APX3330

11 unrelated SAEs in Placebo

Oral APX3330 safety profile consistent with that seen in prior trials

ZETA-1 Clinical Trial Safety Population (subject to final review)

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Summary and Next Steps

APX3330 Product Candidate Profile for Multiple Retinal Indications

Oral, First-In-Class Ref-1 Inhibitor with Favorable Human Safety Data from 12 Completed Trials

APX3330: Well-tolerated Oral Dose up to 600 mg/day | Twice Daily Dosing

MOA and Efficacy Signals in DR

Novel MOA for Treating Retina
↓ Inflammation
↓ Abnormal Angiogenesis
Daily vs. episodic exposure

Good Patient Compliance in ZETA-1 with Convenient Oral Dosing

APX3330 Demonstrated Slowing of Progression of Diabetic Retinopathy

Favorable Safety Profile

Over 350 Subjects (Healthy, Liver, Cancer, Diabetic) Treated
Notably, Several Subjects Dosed ~1 Yr and Others 24-Wks

Few Systemic AEs Across All Doses (120mg-720mg)
< 5% Mild Skin Rash (reversible)
< 5% Mild Diarrhea

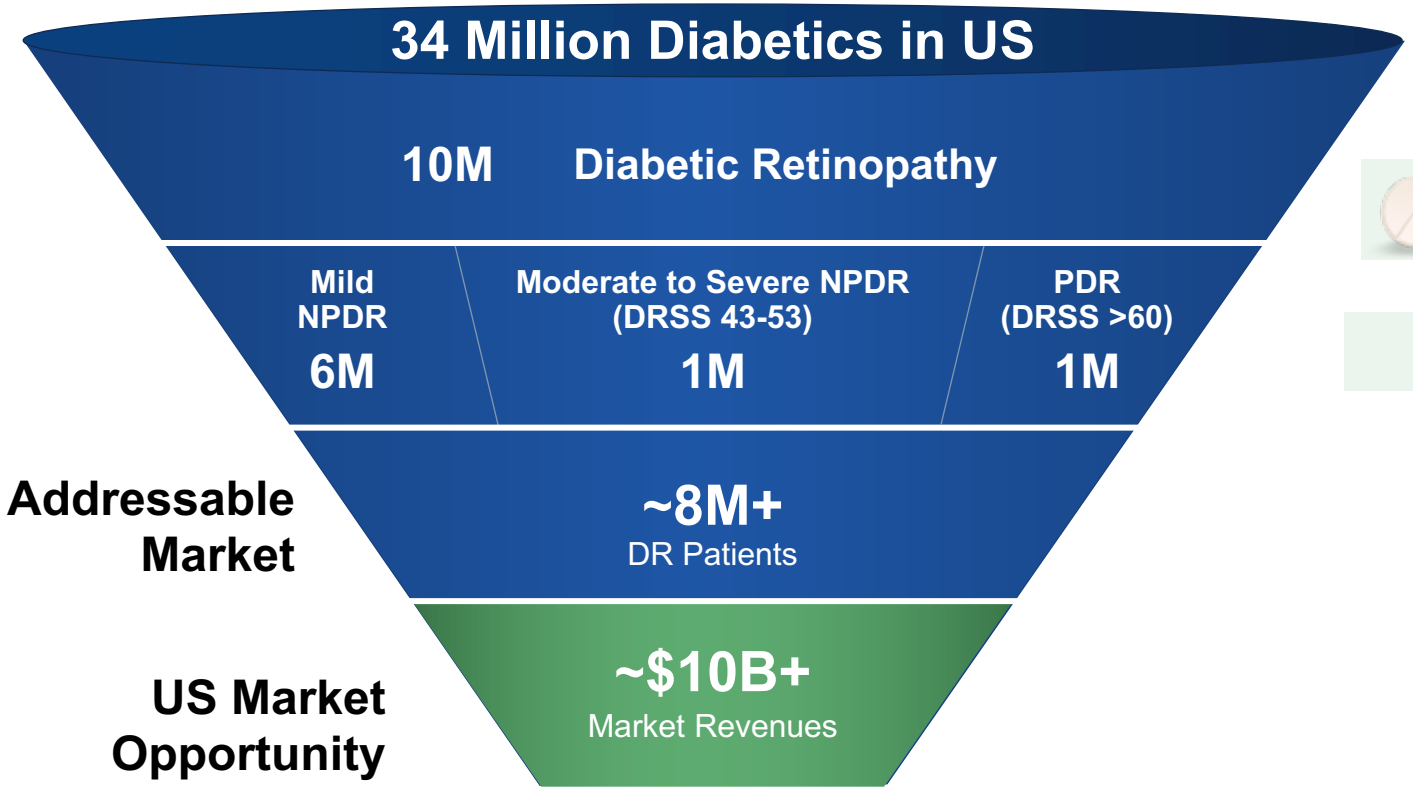
No Treatment-Related Organ Toxicity
(Liver, Cardiovascular {BP, HR}, Kidney, Neurologic, Pulmonary)

Minimal Ocular Side Effects*

Source: ZETA-1 Clinical Trial; *1 subject had vision blur thought to be related by investigator in ZETA-1

Broad Opportunities to Treat Retinal Diseases with APX Platform

APX3330 May Treat Patients Across Retinal Diseases as Single Agent or Adjunctive Therapy



APX3330

APX3330 + Anti-VEGF treatments

APX2009 / APX2014 / APX3330 *(Local Delivery)*

Inflammatory component is common across these retina indications as well & potentially addressable by MOA of Ref-1

DME	Wet AMD	Dry AMD	GA
1M	2M	10M+	1M

Potential First Oral Rx for Retina Diseases with Multi-Billion Revenue Opportunity

Source:
1. American Diabetes Association; International Diabetes Federation; Healthline; *Ocuphire internal analysis and assumptions;
2. 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
3. Patient survey adapted from Lions International Foundation and International Diabetes Foundation-Europe; Meltzer 2000
4. Estimates are provided by the National Eye Institute, FactSheet, Global Data, and Research and Markets. Estimated values are rounded.
5. Estimated prevalence in the U.S.; DME- Diabetic Macular Edema; Age-related Macular Degeneration; Geographic Atrophy; Retinal Vein Occlusion

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Landscape of Systemic Therapies for Diabetic Retinopathy

Ocuphire's APX3330 is the Most Advanced Oral Drug Moving into EOP2 Mtg and Phase 3

Company	Drug	Target/MOA	Indication	Route of Administration	Phase 1	Phase 2	Phase 3	Primary Endpoint/ Secondary Endpoints
Lilly	LY333531	Protein Kinase C inhibitor	DR	Oral	✓	✓	✗ 2006	2002: BCVA 3-line
aerpio pharmaceuticals	çAKB-9778	Tie2	DR	Subcutaneous	✓	✗ 2019		2017: 2-step DRSS @wk24
Ocuphire PHARMA	APX3330	Ref-1 inhibitor (Anti-VEGF and Anti-inflammatory)	DR	Oral	✓	✓		2020: 2-step DRSS @wk24
BAYER	BAY1101042	Guanylate Cyclase activator	DR	Oral	✓	○		2021: 2-step DRSS @wk24
ALKAHEST	AKST4290	CCR3 Eotaxin inhibitor	DR	Oral	✓	✗ 2022		2021: 2-step DRSS @wk24
Roche	RG7774	CB2 receptor (cannabinoid)	DR	Oral	✓	○		2020: 2-step DRSS @wk36
Boehringer Ingelheim	BI 1467335	AOC3	DR	Oral	✓	✗ 2021		2017: Primary:safety@wk12 Secondary: 2-step DRSS@wk12
Valo	OPL-0401	ROCK 1/2 inhibitor	DR	Oral	✓	○		2021: 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*

www.clinicaltrials.gov

APX3330 has Potential to be Early Preventative Therapy for DR Patients

Efficacy Signal

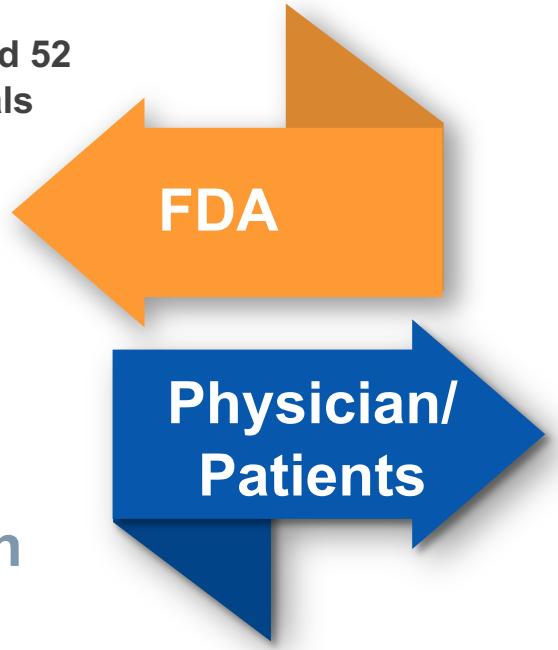
- **Intravitreal:** Percent of patients with ≥ 2 step improvement on the DRSS score at week 24 and 52 compared to placebo in 2 well-controlled trials
- **Systemic: Percent of patients with ≥ 3-step worsening on binocular DRSS at week 24 and 52 compared to placebo in 2 well-controlled trials**

Safety

- Approval depends on a product's benefit outweighing its risks in the intended population, this benefit should be evaluated in multi-center, 2-year clinical trials

Non-Invasive Treatment Option

- FDA does not require comparative arm of approved anti-VEGF injections (Eylea) for DR



Efficacy Signal

- Clinically meaningful decrease in diabetic retinopathy severity

OR

- Early intervention with oral may prevent progression of DR to vision loss

Safety

- No major organ toxicities
- Well-tolerated (e.g., AEs acceptable if mild and infrequent for oral)

Non-Invasive Treatment Option

- Eylea®, although approved, is currently not used as standard of care because of the treatment burden for asymptomatic DR patients
- Ability to be prescribed by wide-range of healthcare providers (ophthalmologists, optometrists, endocrinologists, primary care, etc.)
- Oral option increases global access, especially in underserved regions

Eylea® label; APX3330 Investigator Brochure, ZETA-1 clinical trial

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Key Takeaways and Next Steps

Key Takeaways

- APX3330 is the most advanced oral program in development for diabetic eye disease
- APX3330 demonstrated favorable safety with compelling potential to slow progression of diabetic retinopathy
- ZETA-1 statistically significant results on ‘binocular 3-step worsening DRSS' endpoint provides a potential Phase 3 registration endpoint

Next Steps

- Further analysis of ZETA-1 Phase 2 data, including insights for Phase 3 registration trial design
- Plan for the EOP2 FDA meeting for APX3330 in DR indication
- Data presentations at medical meetings
- Advance APX3330 development (cGMP drug, NDA-enabling work, first Phase 3 trial, regional partnerships) → fully funded into 2025

Goal

To have a clinically meaningful impact on ***preventing progression*** to reduce likelihood of vision loss in diabetic retinopathy patients

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Upcoming Catalysts:

- ✓ *Topline Results APX3330 ZETA-1 P2b trial for DR/DME (Early 2023)*
- *EOP2 FDA Meeting for APX3330 (2H 2023)*
- *Pivotal Phase 3 Trials for Nyxol in Presbyopia with 1st Data Readouts (Late 2023)*
- *Potential Approval of 1st Nyxol NDA (Late 2023)*

Stock Price[1]	$3.67
Market Cap[1]	$77M
Cash (Pro-Forma)[2,3]	~$49 M
Shares Outstanding[2]	20.8M
Average Daily Volume	~200k Shares
Cash Runway Into 2025	

[1] As of close on January 24, 2023; [2] End of 3Q22 (10-Q); [3] Includes upfront payment from License Agreement

Corporate Highlights

Two Lead Clinical-Stage Novel Drugs Addressing Multiple Large Ophthalmology Markets (~$20B US total) with Limited to No Competition & Patent Coverage to 2034+

APX3330 oral tablets

Diabetic Retinopathy/Diabetic Macular Edema (DR/DME) – diabetic eye disease

Nyxol preservative-free eyedrops

Reversal of Mydriasis (RM) – eye dilation

Presbyopia (P) – age-related blurry near vision

Night Vision Disturbances (NVD) – halos, glares, starbursts

Successful Execution of 5 Trials in Last 2 Years with 6 Positive Phase 3 & Phase 2 Data Read-outs for Nyxol in RM, Presbyopia, and NVD

NDA submitted Nov 2022 for Nyxol's first indication in RM

Global License Agreement Signed in Late 2022 with Viatris to Develop and Commercialize Nyxol for All Indications in the US and Globally

Strong Financial Position (with No Debt) to Support Operations into 2025 and Coverage from 5 Biotech Research Analysts

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Thank You and Q&A