

# Transforming Patient Outcomes with Superior Vision Gains

**Corporate Overview | January 2025** 

NASDAQ (OPT); ASX (OPT.AX)



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# Sozinibercept Has the Potential to Be the First Product in 20 Years to Deliver Superior Visual Outcomes

#### Addressing High Unmet Need

- Despite wide use of anti-VEGF-A therapy, wet AMD patients still experience loss in vision long term<sup>1</sup>
- Every letter of vision counts to improve quality of life and reduce mortality

# **Proprietary Technology**

- First-in-class VEGF-C/D 'trap' inhibitor intended for combination with standard of care anti-VEGF-A therapies
- Composition of Matter and Methods of Use Patents through 2034; opportunities to extend beyond 2034\*

#### Superior Lead Asset

- Phase 2b demonstrated superiority in combination with SOC therapy, with well tolerated safety profile
- Sozinibercept has the potential to improve vision for millions of patients with wet AMD

# **Topline Data from Pivotal Trials in 2025**

- Topline data anticipated for COAST (n=998) in early 2Q CY2025 and ShORe (n=986) in mid-CY2025
- Current cash expected to fund operations into 3Q CY2025<sup>2</sup>

# Substantial Market Opportunity

- Multibillion dollar commercial opportunity in a growing market with an established clinical practice
- Sozinibercept developed for use in combination with any anti-VEGF-A; will not compete directly with SOC therapies

AMD – age-related macular degeneration; MOA – Mechanism of Action; SOC – Standard of care

<sup>&</sup>lt;sup>1</sup>CATT Research Group; Maguire MG et al. Ophthalmology. 2016 Aug.

<sup>&</sup>lt;sup>2</sup>Additional funding will be required to reach commercialization of sozinibercept and to meet obligations under the Development Funding Agreement ("DFA"). As a result of obligations under the DFA and applicable law regarding liquidity, the Company may raise or obtain additional capital in one or more transactions, earlier than 3Q CY 2025 or anticipated topline data readout dates.

<sup>\*</sup>Potential for Patent Term Extensions & Data and Market Exclusivity (12 Years for Biologic)

# Sozinibercept Designed to Deliver Superior Visual Outcomes in Combo with VEGF-A Inhibitors; Potential to Create New Multi-Billion Dollar Medicine

#### **Global Marketed VEGF-A Inhibitors**



#### Sozinibercept is a VEGF-C/D "Trap" Inhibitor



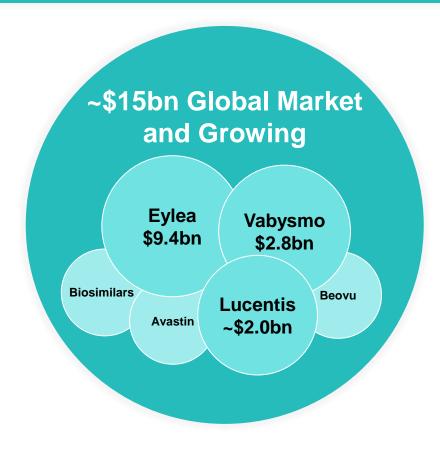
#### **Targeting Improved Visual Function**

Critical for Patients, Physicians and Payors

**Fits Seamlessly into Physician Practice** 

**Potential Use with Any VEGF-A Inhibitor** 

**Multi-Billion Dollar Commercial Opportunity** 



### **Experienced Leadership Team**

### Expertise and Track Record to Make a Positive Impact on the Retinal Community

#### **Management Team**



Fred Guerard, PharmD, MS
Chief Executive Officer





Tom Reilly
Chief Financial Officer





Parisa Zamiri, MD, PhD Chief Medical Officer





Megan Baldwin, PhD, MAICD Founder, Chief Innovation Officer

Genentech



Mike Campbell
Chief Commercial Officer



#### **Chief Medical Advisor**



Arshad M. Khanani, MD, MA, FASRS

Managing Partner, Director of Clinical Research
and Director of Fellowship at Sierra Eye

Associates, and Clinical Professor at the University
of Nevada, Reno School of Medicine

#### **Clinical Advisory Board**



Charles C. Wykoff, MD, PhD
Director of Research, Retina Consultants of Texas,
Chairman of Research and Clinical Trials
Committee, Retina Consultants of America



**Tim Jackson, PhD, MB, ChB, FRCophth**National Health Service, Consultant at Kings
Hospital College Hospital, London



Jason Slakter, MD
Clinical Profession at New York University School
of Medicine and partner at Vitreous Retina Macula
Consultants of New York

# Improving Vision Now the Largest Unmet Need in Wet AMD for Retina Specialists

#### **ASRS PAT Survey 2023**

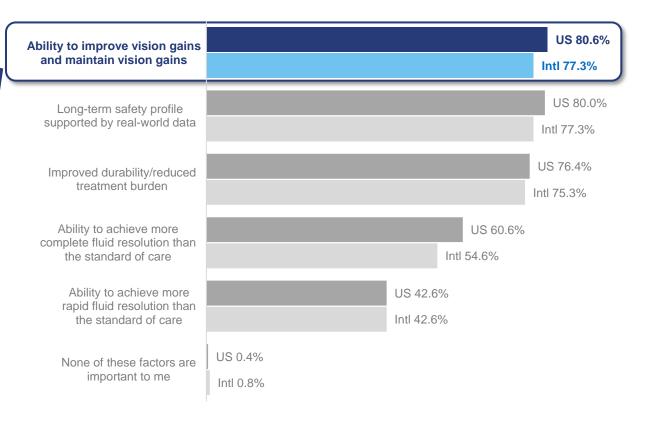
What are the greatest unmet needs in treating wet AMD and DME? n=1,012

#### US 78.6% Greater durability Intl 74.3% US 50.4% Improve vision Intl 55.2% US 47.1% Longer VEGF supression Intl 58.2% US 29.5% Stable anatomy Intl 45.5% US 1.5% Other Intl 0.4% US 1.1% None of the above

Intl 0.0%

#### **ASRS PAT Survey 2024**

Which factors are more important to you when selecting an anti-VEGF agent? n=1,021



# Despite Treatment with Standard of Care Anti-VEGF-A Therapies, the Majority of Patients Achieve Suboptimal Vision Outcomes

### **Despite treatment with anti-VEGF-A therapy\***

>45% do not achieve significant vision gains

>60% will have persisting macular fluid

25% will have further vision loss at 12+ months



The majority of patients fail to achieve 20/40 vision<sup>1</sup>



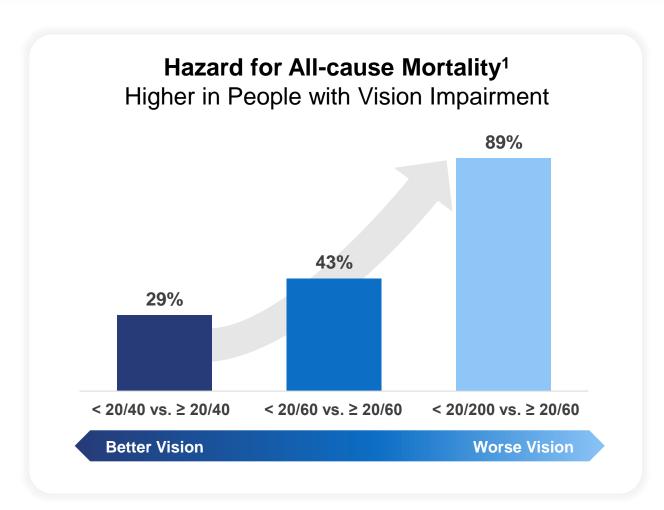
Suboptimal vision is associated with decrease in Instrumental Activities of Daily Living (IADL) skills<sup>2</sup>

<sup>\*</sup>Based on randomised, controlled clinical trial data; >45% fail to achieve ≥ 2 lines improvement in Best Corrected Visual Acuity (BCVA); Persisting fluid: SD-OCT CST ≥ 300 µM or Time-Domain OCT CST ≥ 250 µM IADL: Instrumental activities of daily living (complex activities related to the ability to live independently)

<sup>&</sup>lt;sup>1</sup>Mettu PS, et al. Prog Retin Eye Res. 2021

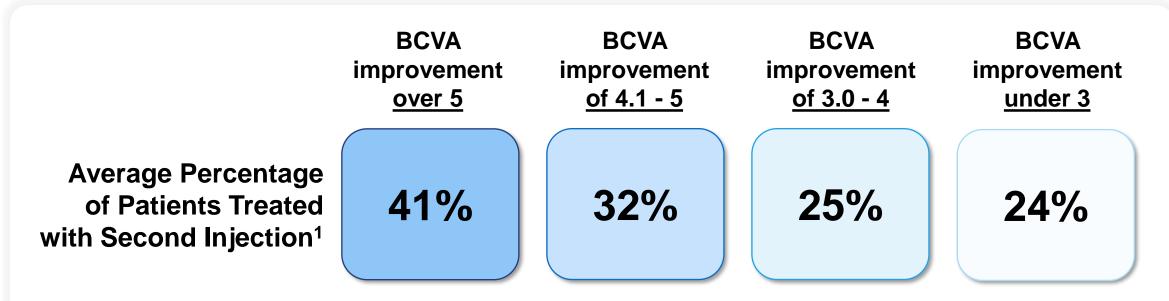
<sup>&</sup>lt;sup>2</sup>Hochberg C, et al. Invest Ophthalmol Vis Sci. 2012 May 31.

### Every Letter Counts; Vision Loss Associated with Increased Mortality Risk



Decrease of 1 ETDRS letter per year expected to increase mortality risk by 16%<sup>2</sup> associated exclusively with IADL levels

# U.S. Retina Specialists Willing to Administer Second Injection to at Least 24% of Their Patients for Additional BCVA Improvement



What percentage of your Wet AMD patients would you use a second injection (anti-VEGF C/D) immediately after an anti-VEGF-A injection at various levels of BCVA improvement of the combination over SoC? (Among Total Respondents, Avg. % of Patients\*, n=125)

### Estimate 1% Share of Wet AMD TAM Equals ~\$100M+ in Sales Per Annum

BCVA – Best Corrected Visual Acuity TAM – Total Addressable Market

<sup>&</sup>lt;sup>1</sup>Source: InCrowd Awareness Trial and Usage (ATU) Report, June 2024

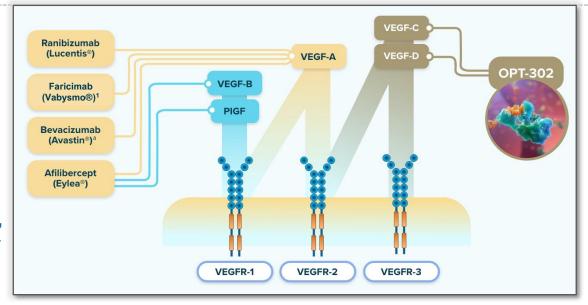
<sup>\*</sup>Averages calculated using the midpoints of each % prescribing allocation group.

# Sozinibercept, a First-In-Class VEGF-C/D "Trap" Inhibitor, Has the Potential to Address the Limitations of Anti-VEGF-A Therapies



#### **The Problem**

Wet AMD is a multi-factorial disease. Treatment with VEGF-A inhibitors upregulates VEGF-C/D, driving angiogenesis and vascular permeability.





#### **The Solution**

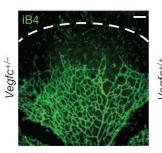
When used in combination with any VEGF-A inhibitor, OPT-302 completely blocks VEGFR-2 and VEGFR-3 signaling.

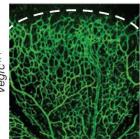
<sup>&</sup>lt;sup>1</sup> Faricimab also has inhibitory effect on Ang-2.

<sup>&</sup>lt;sup>a</sup> Bevacizumab is used 'off-label' for the treatment of neovascular (wet) AMD

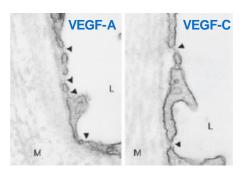
# Published Evidence Supports Broader VEGF Pathway Inhibition with Sozinibercept

#### **VEGF-C Stimulates Retinal Angiogenesis^**

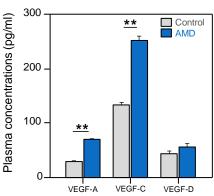




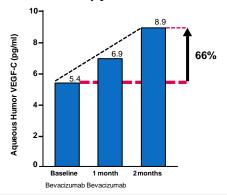
VEGF-A and VEGF-C Induce Vascular Leakage/permeability#



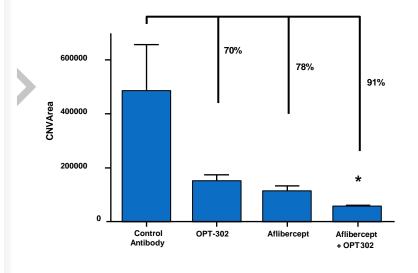
Circulating VEGF-C Levels Significantly Elevated in AMD Patients<sup>↑</sup>



Elevated VEGF-C in Aqueous Humor Following Anti-VEGF-Atherapy in Wet AMD Patients\*

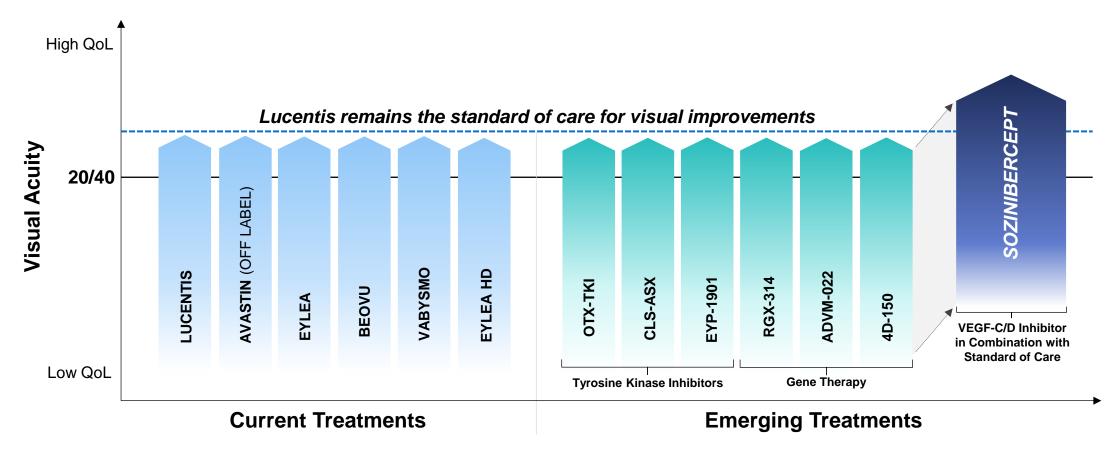


# Additive Benefit of VEGF-A and VEGF-C/D Inhibition in Mouse Wet AMD Model



# Sozinibercept Has Demonstrated Improvement in Vision Gains and Reduction in Vision Loss

### Opportunity in Wet AMD Market for an Overall Shift Towards Superior Visual Outcomes



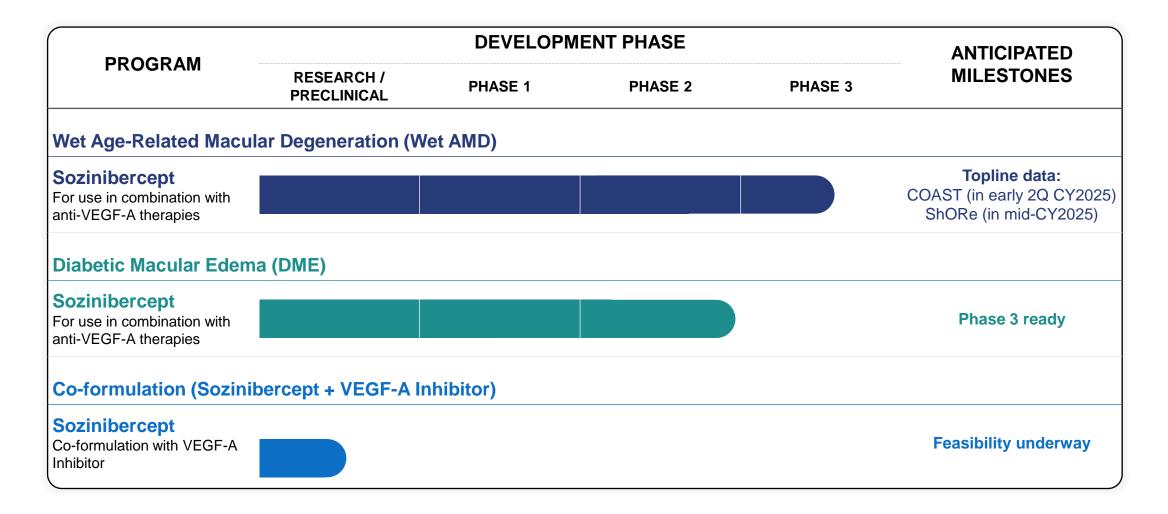
QoL - Quality of Life

Jackson, Timothy L., et al. "A randomized controlled trial of OPT-302, a VEGF-C/D inhibitor for neovascular age-related macular degeneration." Ophthalmology. June 2023. Jung, Eric, et. al. "The future of wet AMD therapeutics." Retina Today. November/December 2023.

Comparison of historical data; other than Lucentis, comparative data is not from the same study. These results are presented from different clinical trials at different points in time with differences in trial design. Cross-trial comparisons must be interpreted with caution, and as a result, conclusive cross-trial comparisons cannot be made.

# Long-term Value Opportunities for Sozinibercept

Main Patent Family Extends through 2034, with Expansion Opportunities Beyond 2034\*



# Advancing Therapeutic Innovations to Transform Patient Outcomes with Superior Vision Gains

### We are dedicated to advancing sozinibercept to improve patients' visual outcomes

**Clinical Milestones** 

- Phase 3 program enrolled 1,984 patients across COAST and ShORe
- Topline data anticipated for COAST in early 2Q CY2025 and ShORe in mid-CY2025

Manufacturing Scale-up

Steps

Next

- DS PPQ campaign completed Sep-2024; update on DP PPQ in early CY2025
- PPQ validation batches supportive of BLA filing and launch

Regulatory Preparations

- FDA Fast Track designation allows rolling submission of completed BLA modules
- Potential BLA approval anticipated as early as end of CY2026

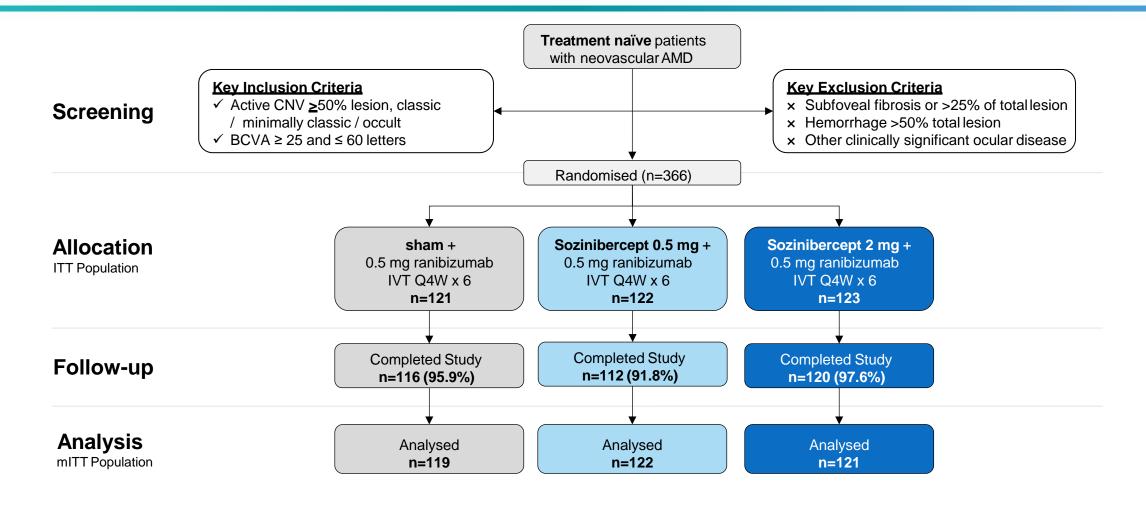
Commercial Readiness

- Strengthen medical expert engagement and develop market access strategy
- Complete development of product launch plan

DS: Drug Substance; DP: Drug Product

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# Robust Phase 2b Trial in Wet AMD Demonstrated Superiority in Visual Outcome



# Phase 2b Primary and Secondary Endpoints Pre-Specified Anatomical Sub-Groups Informed Enrichment of Phase 3 Program

### **Primary Endpoint**

Mean change from baseline in BCVA at week 24

### **Key Secondary Endpoints**

Proportion of patients gaining ≥15 letters from baseline at week 24

Change in central subfield thickness (CST) from baseline at week 24

Change in intra-retinal and sub-retinal fluid from baseline to week 24

Safety and tolerability

#### **Select Pre-specified Subgroups**

Predominantly classic, minimally classic, & occult lesions (Stratification Factor)

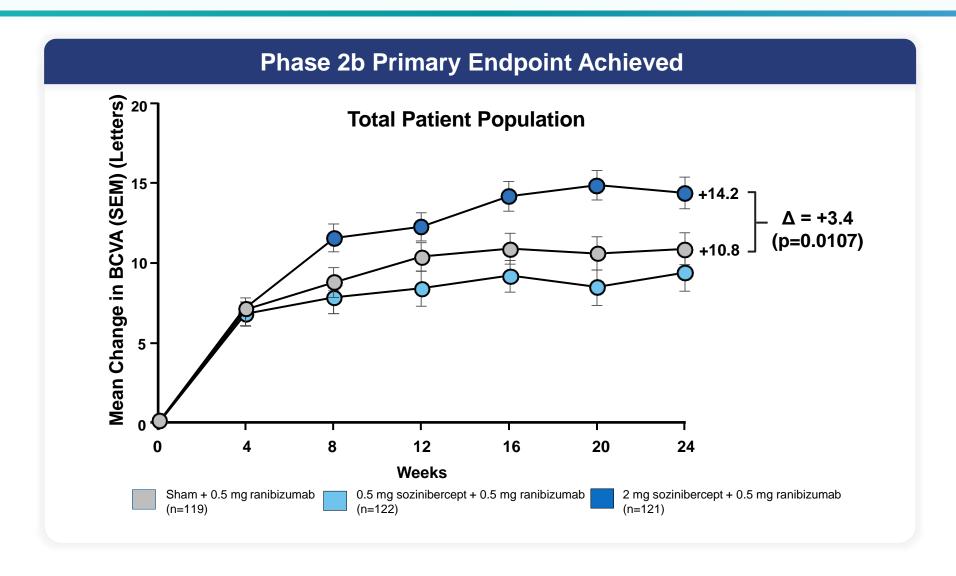
Retinal Angiomatous Proliferation (RAP) detected/not detected at baseline

Polypoidal Choroidal Vasculopathy (PCV)
detected/not detected at baseline

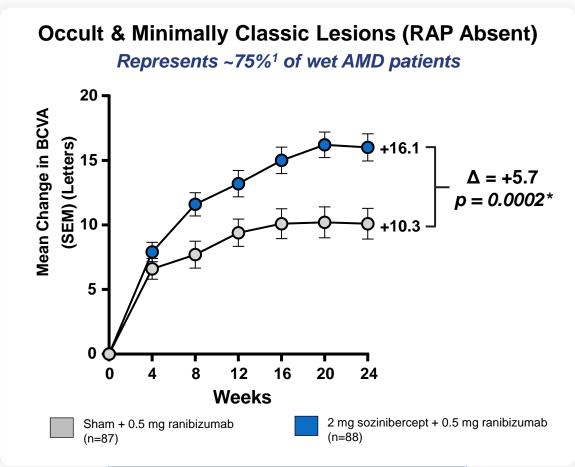
### Well-Balanced Phase 2b Trial Demographics and Baseline Characteristics

Demographic/Baseline Disease Characteristic		Sham + ranibizumab n=121	0.5 mg sozinibercept + ranibizumab n=122	2 mg sozinibercept + ranibizumab n=123
Mean Age - years ± SD		76.1 ± 9.48	78.8 ± 8.16	77.8 ± 8.82
0	Male	48 (39.7%)	49 (40.2%)	45 (36.6%)
Sex - n (%)	Female	73 (60.3%)	73 (59.8%)	78 (63.4%)
Caucasian Race – n (%)		117 (99.2%)	119 (99.2%)	117 (97.5%)
Mean Visual Acuity (BCVA) - letters ± SD		50.7 ± 10.21	51.1 ± 8.96	49.5 ± 10.26
Mean Total Lesion Area - mm² ± SD		6.08 ± 3.21	6.48 ± 3.30	6.62 ± 3.39
Lesion Type	Predominantly classic -n (%)	15 (12.4%)	15 (12.3%)	16 (13.0%)
	Minimally classic -n (%)	53 (43.8%)	51 (41.8%)	53 (43.1%)
	Occult - n (%)	53 (43.8%)	56 (45.9%)	54 (43.9%)
	PCV detected <sup>1</sup> -n (%)	20 (16.5%)	24 (19.7%)	22 (17.9%)
	RAP detected <sup>2</sup> -n (%)	15 (12.7%)	22 (18.5%)	14 (11.8%)
Mean central subfield thickness (CST) - mm ±SD		412.10 ± 110.62	425.18 ± 120.45	414.12 ± 123.25
Sub-retinal fluid (SRF) present – % participants		89.3%	84.4%	87.8%
Intra-retinal cysts present –% participants		57.9%	63.9%	56.1%

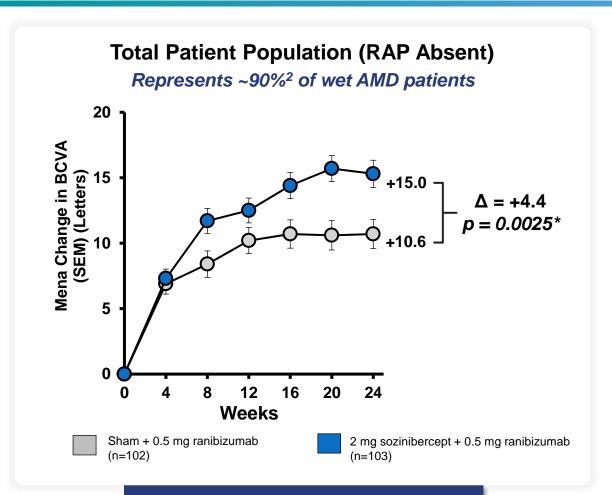
# Sozinibercept 2 mg Combination Therapy Demonstrated Over 30% Improvement in Visual Acuity over Ranibizumab Monotherapy



### Phase 2b Superiority Data Informed Enrichment of Phase 3



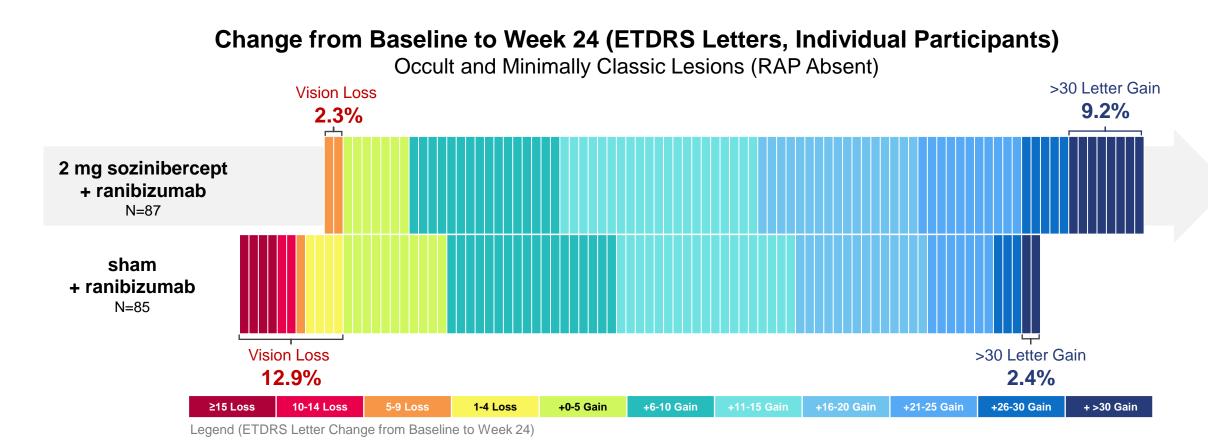




2<sup>nd</sup> Primary Analysis Population in Phase 3

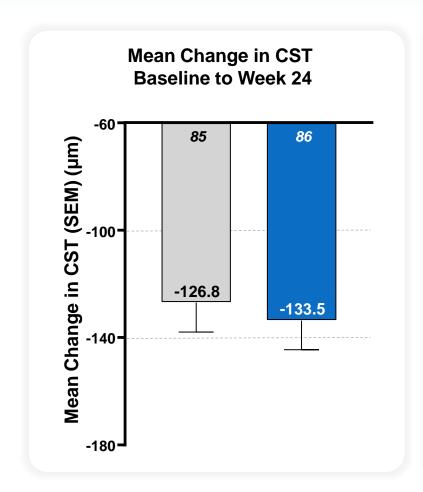
<sup>\*</sup>Unadiusted p-value:

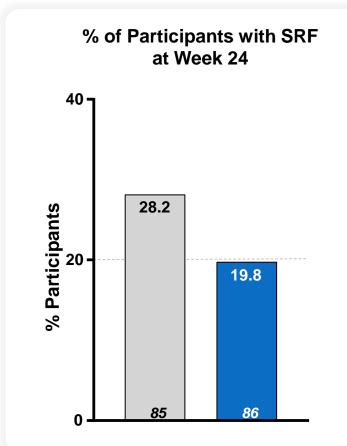
# Greater Proportion of Sozinibercept Patients Gained Substantial Vision and Fewer Experienced Vision Loss

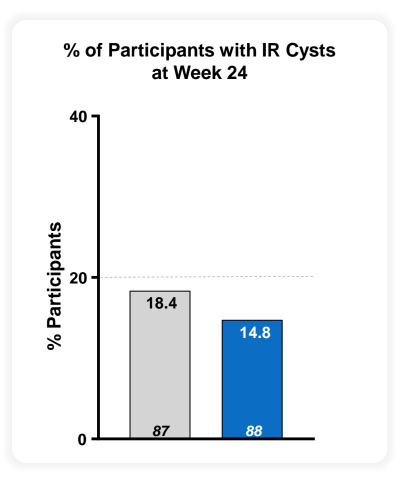


42% relative increase in patients achieving 20/40 vision compared to ranibizumab control

### Sozinibercept Reduced Retinal Thickness and Dried the Retina Better







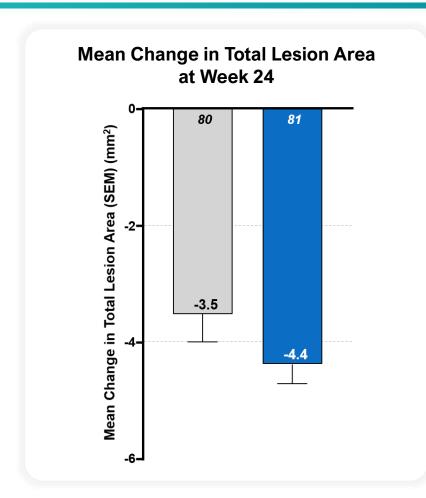


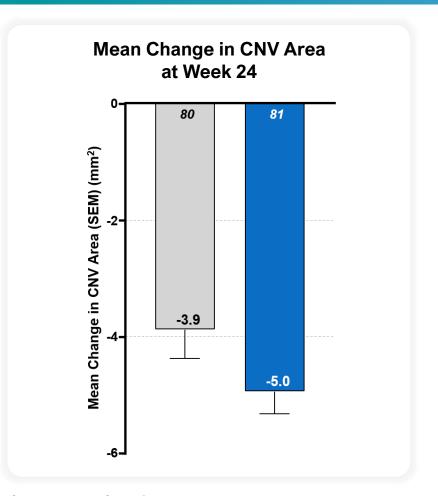
Sham + 0.5 mg ranibizumab

2

2 mg sozinibercept + 0.5 mg ranibizumab

### Sozinibercept Demonstrated Greater CNV and Lesion Regression



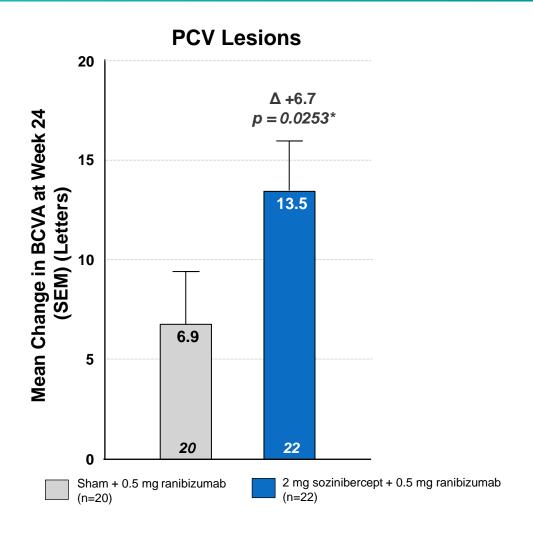




Sham + 0.5 mg ranibizumab (n=80)

2 mg sozinibercept + 0.5 mg ranibizumab (n=81)

### Superior Vision Gains in Hard-To-Treat PCV Lesion Patients



Polypoidal Choroidal Vasculopathy (**PCV**) is a difficult-to-treat wet AMD subtype; it is often described as the **most prevalent form of** wet AMD worldwide

PCV is **highly prevalent in Asian populations** (up to ~60%), while ~8-13% prevalence in Caucasians

Phase 3 ShORe and COAST trials enrolled patients with PCV<sup>1</sup>

<sup>\*</sup>Unadjusted p-value

<sup>&</sup>lt;sup>1</sup> Evaluated by color fundus photography (FP), fluorescein angiography (FA), and spectral domain optical coherence tomography (SD-OCT)

### Sozinibercept Was Well Tolerated

Safety of Combination Therapy Comparable to Standard of Care Monotherapy

N Participants (%)	Sozinibercept Any dose* N=399 (N=1,842 injections)	Sozinibercept 2 mg N=263 (N=1,121 injections)	Sham + anti-VEGF-A control N=170 (N=854 injections)
Ocular TEAEs - Study Eye – related to study product(s)	41 (10.2%)	22 (8.4%)	20 (11.8%)
Ocular TEAEs - Study Eye - Severe	4 (1.0%)	2 (0.8%)	2 (1.2%)
Intraocular inflammation – Study Eye	71,2,3 (1.8%)	31 (1.1%)	31 (1.8%)
Participants with AEs leading to treatment discontinuation	42,4-6 (1.0%)	14 (0.4%)	27,8 (1.2%)
Any APTC event	44,5,9,10 (1.0%)	35,9,10(1.1%)	211,12 (1.2%)
Deaths	210,13 (0.5%)	210,13 (0.8%)	214,15 (1.2%)

<sup>&</sup>lt;sup>1</sup>Transient anterior chamber cell (trace 1-4 cells); <sup>2</sup> SAE of endophthalmitis, with AE's of hypopyon and anterior chamber cell (n=1; 0.5 mg); <sup>3</sup> SAE of vitritis (n=1; 0.5 mg); <sup>4</sup>Non-fatal myocardial infarction; <sup>5</sup>Cerebrovascular accident; <sup>6</sup>Enteritis; <sup>7</sup>Abdominal pain; <sup>8</sup>Increased IOP; <sup>9</sup> Non-fatal angina pectoris; <sup>10</sup>Fatal congestive heart failure/myocardial infarction; <sup>11</sup>Non-fatal arterial embolism; <sup>12</sup>Embolic stroke; <sup>13</sup>Metatstaic ovarian cancer; <sup>14</sup> Pneumonia; <sup>15</sup> infective endocarditis.

<sup>\*</sup>Any dose (sozinibercept 0.3 mg, 0.5 mg, 1 mg or 2 mg)

# Similar Rate of Intraocular Inflammation Between Standard Of Care and Sozinibercept in Combination Therapy

N Participants (%)	Sozinibercept Any dose* N=399 (N=1,842 injections)	Sozinibercept 2 mg N=263 (N=1,121 injections)	Sham + anti-VEGF-A control N=170 (N=854 injections)
Intraocular Inflammation <sup>1</sup>	7 (1.8%)	3 (1.1%)	3 (1.8%)
OPT-302-1001 (Phase 1/2a wet AMD)	2	0	0
Uveitis with anterior chamber cell 1+	1	0	0
Uveitis with anterior chamber cell 2+	1	0	0
OPT-302-1002 (Phase 2b wet AMD)	3	1	2ª
Endophthalmitis with anterior chamber 1+ and hypopyon	1	0	0
Vitritis	1	0	0
Anterior chamber cell, trace	1	1	2ª
OPT-302-1003 (Phase 1b/2a DME)	2 <sup>b</sup>	2 <sup>b</sup>	1
Iritis with keratic precipitates and anterior chamber cell 2+	1	1	0
Iritis with anterior chamber cell 2+	0	0	1
Anterior chamber cell 4+, associated with cataract extraction/ intraocular lens implant and hyphema	1 <sup>b</sup>	1 <sup>b</sup>	0

Safety population

<sup>&</sup>lt;sup>1</sup>AEs observations considered to be indicative of intraocular inflammation, defined prior to database lock

<sup>&</sup>lt;sup>a</sup>Observed during ophthalmic examination, but not reported as TEAEs

<sup>&</sup>lt;sup>b</sup>Considered associated with lens extraction and not reported as TEAEs

# Phase 3 Clinical Program Is Informed by Phase 2b Results and Optimized for Success



Enriched patient population by excluding RAP lesions (+4.4 letters in Phase 2b); key inclusion and exclusion criteria otherwise unchanged



Hierarchical primary analysis first conducted in the high-responding occult and minimally classic population (+5.7 letters in Phase 2b) followed by total patient population



Two robust pivotal trials studying sozinibercept in combination with Eylea® and Lucentis® in treatment naïve patients with wet AMD



Phase 3 designed to support broad label for use in combination with any VEGF-A inhibitor for all wet AMD patients (treatment naïve and prior treated)

# Global Pivotal Program Involves 33 Countries and ~400 Sites

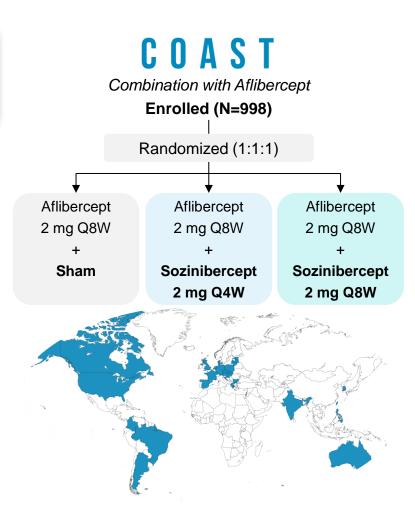
Multi-center, sham controlled, double-masked trials in **treatment** naïve wet AMD patients

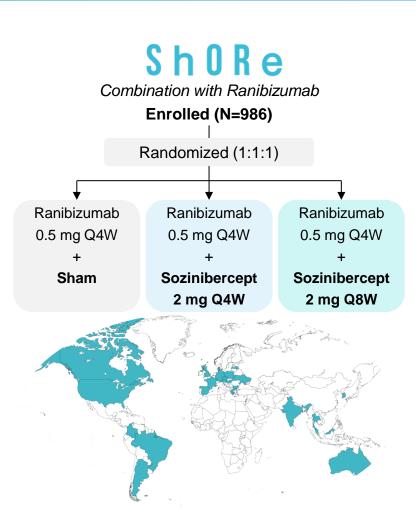
#### **Key Inclusion Criteria**

- ✓ Active CNV >50% lesion: classic, minimally classic, occult
- ✓ BCVA ≥ 25 and ≤ 60 letters

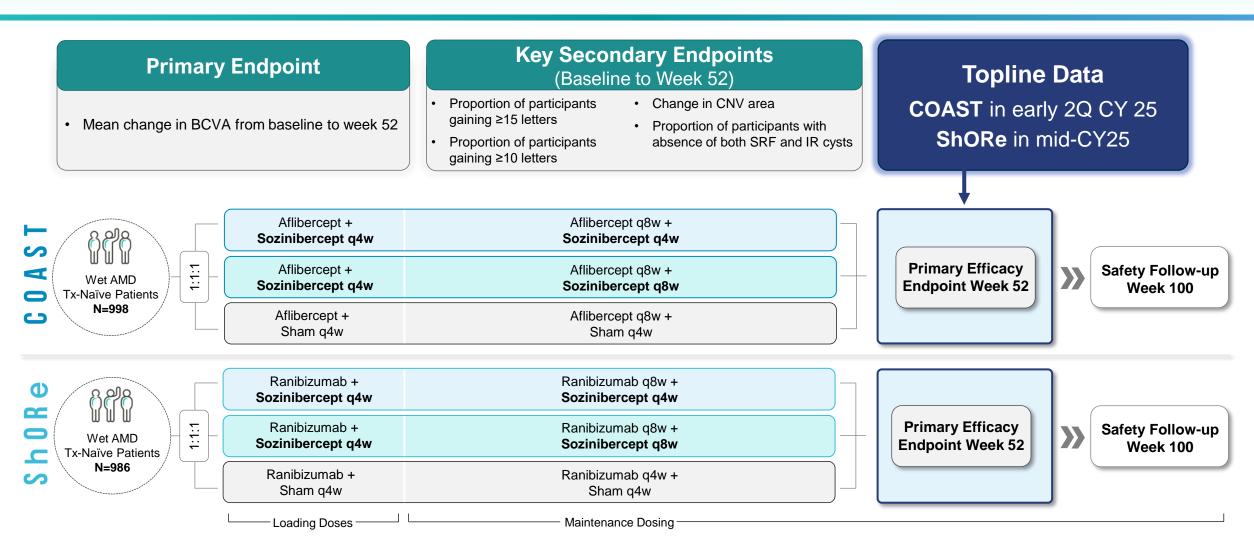
#### **Key Exclusion Criteria**

- Subfoveal fibrosis or >25% of total lesion
- × Hemorrhage >50% total lesion
- × Other clinically significant ocular disease
- x RAP lesions





# Pivotal Trial Design Supports Potential Broad Label for Use With Any Anti-VEGF-A Therapy



# Phase 3 Enrolled a Higher Proportion of Patients With Best Responding Lesion Types Compared to Phase 2b

		Phase 2b		Phase 3	
Demographic/Baseline Disease Characteristic		Sham + ranibizumab n=121	2 mg sozinibercept + ranibizumab n=123	COAST N=997*	ShORe N=985*
Mean Age - years ± SD		76.1 ± 9.48	77.8 ± 8.82	74.8 ± 8.02	75.4 ± 8.47
Sex – n (%)	Male	48 (39.7%)	45 (36.6%)	442 (44.3%)	456 (46.2%)
	Female	73 (60.3%)	78 (63.4%)	556 (55.7%)	530 (53.8%)
Race – n (%)	Caucasian	117 (99.2%)	117 (97.5%)	859 (86.1%)	825 (83.7%)
	Asian	0 (0.0%)	0 (0.0%)	85 (8.5%)	134 (13.6%)
Mean Visual Acuity (BCVA) - letters ± SD		50.7 ± 10.21	49.5 ± 10.26	52.5 ± 9.43	52.2 ± 9.12
Mean Total Lesion Area - mm² ± SD		6.08 ± 3.21	6.62 ± 3.39	6.38 ± 3.20	6.37 ± 3.09
	Occult - n (%)	53 (43.8%)	54 (43.9%)	555 (55.7%)	568 (57.6%)
	Minimally classic –n (%)	53 (43.8%)	53 (43.1%)	340 (34.1%)	334 (33.9%)
Lesion	Predominantly classic – n (%)	15 (12.4%)	16 (13.0%)	102 (10.2%)	84 (8.5%)
	PCV detected1-n (%)	20 (16.5%)	22 (17.9%)	261 (26.2%)	236 (23.9%)
	RAP detected <sup>2</sup> -n (%)	15 (12.7%)	14 (11.8%)	<del></del>	_
Mean central subfield thickness (CST) - mm ±SD		412.10 ± 110.62	414.12 ± 123.25	446.5 ± 139.7	451.7 ± 137.8
Sub-retinal fluid (SRF) present – % participants		89.3%	87.8%	95.8%	94.3%
Intra-retinal cysts present – % participants		57.9%	56.1%	78.6%	83.7%

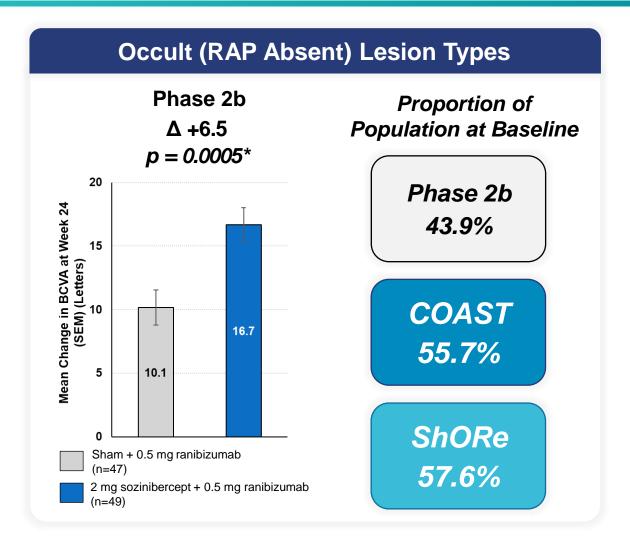
SD – standard deviation; BCVA – Best Corrected Visual Acuity

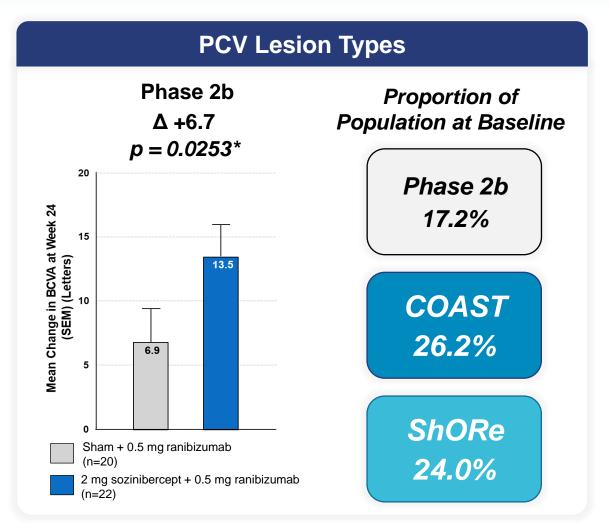
<sup>\*</sup>Intent-to-Treat (ITT) population; 1 patient in each of COAST and ShORe was randomized but not treated

<sup>&</sup>lt;sup>1</sup>PCV - polypoidal choroidal vasculopathy, detected by SD-OCT, FA and fundus photography.

<sup>&</sup>lt;sup>2</sup>RAP - retinal angiomatous proliferation, detected by SD-OCT, FA and fundus photography.

# Higher Proportion of Patients With Best Responding Lesion Types





# Cash Runway Through Both Pivotal Topline Data Readouts

Financial Overview			
Ticker	OPT (ASX/NASDAQ)		
Shares Outstanding <sup>1</sup>	Ordinary Shares: 1,231.1M ADS equivalents: 153.9M		
Cash/Cash Equivalents <sup>2</sup>	US\$130M		
Offices	Melbourne, Australia Princeton, NJ		

### **Development Funding Agreement (DFA)**

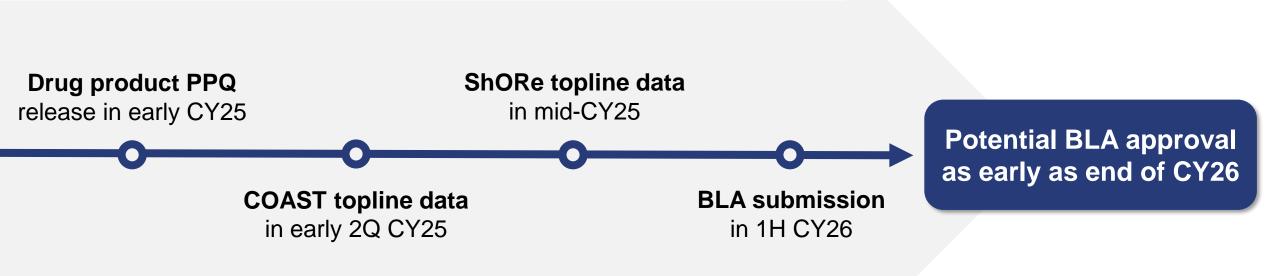
- Total funding drawn under DFA: US\$170M
- Provides non-dilutive funding for development of sozinibercept
- If sozinibercept is approved, repayment is capped at 4x investment and split between fixed payments and variable payments at 7% of revenues
- No amounts owed if the clinical trials do not meet the primary endpoint or if regulatory approval is not received<sup>3</sup>

<sup>&</sup>lt;sup>1</sup>As of June 30, 2024, pro-forma for the 2024 Retail Entitlement Offer which closed in July 2024.

<sup>&</sup>lt;sup>2</sup>Prelminary, unaudited estimate as of December 31, 2024, subject to change upon completion of Opthea's financial statement closing procedures.

In certain circumstances, upon or following the termination of the DFA, the Company may owe the DFA investors a multiple of amounts paid to the Company under the DFA. Please refer to the description of the DFA included in the Company's Form 6-K filed with the SEC on August 15, 2022 and the DFA filed as Exhibit 4.14 to the Company's Annual Report on Form 20-F filed with the SEC on September 29, 2022 for more information. Note: Additional funding will be required to reach commercialization of sozinibercept and to meet obligations under the DFA. As a result of obligations under the DFA and applicable law regarding liquidity, the Company may raise or obtain additional capital in one or more transactions, earlier than 3Q CY 2025 or anticipated topline data readout dates.

# Anticipated Clinical and Manufacturing Timelines Support BLA Submission in 1H26 and Potential Approval by End of CY2026





### Thank You.

#### **UPCOMING EVENT:**

### **Opthea Investor Days**

Discuss commercial insights and readiness plans

Location	Time	Format
New York City	Jan 28 1:30 pm EST	In-person & virtual
Sydney	Feb 3 4:30 pm AEDT	In-person
Melbourne	Feb 5 4:30 pm AEDT	In-person

Details under "Events & Presentations" of the Investor section of Opthea website

