



# Long-Term Outlook

Shankar Musunuri, PhD, MBA  
Chairman of the Board, CEO & Co-founder

R&D Day  
November 1, 2022



# Forward Looking Statements

*This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are based on the beliefs and assumptions of Ocugen, Inc. and on information currently available to management. All statements contained in this presentation other than statements of historical fact are forward-looking statements. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled “Risk Factors” in the quarterly and annual reports that we file with the SEC.*

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# We're Here to Make an Impact Through *Courageous Innovation*

**Mission:** Developing cutting-edge innovations for people facing serious disease and conditions with a commitment to ensuring global market access

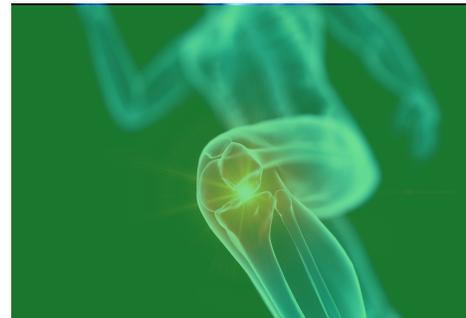
**Pioneering modifier gene therapy** for inherited retinal diseases, as well as larger blindness diseases with unmet need



**Innovating a novel biologic** to treat eye diseases that can lead to vision loss for millions of people



**Developing vaccines** to provide choice to Americans in the fight against **COVID-19**



**Pursuing Regenerative Cell Therapy** to treat serious conditions like articular cartilage lesions

# Pipeline Overview

	Asset/Program	Indication	Current Status
Vaccines	COVAXIN™ (BBV152) SARS-CoV-2 virus	COVID-19	<ul style="list-style-type: none"> <li>EUA for adults in Mexico; EUA for 5 to 18-year-olds submitted</li> <li>Recruitment completed for U.S. Phase 2/3 Immuno-bridging and broadening clinical trial</li> </ul>
	OCU500 Mucosal vaccine	COVID-19	<ul style="list-style-type: none"> <li>License secured from Washington University</li> <li>Phase 1/2 pending FDA discussions</li> </ul>
Cell therapies (Regenerative Medicine)	NeoCart® (Autologous chondrocyte-derived neocartilage)	Treatment of Articular Cartilage Defects in the Knee	U.S. Regenerative Medicine Advanced Therapy (RMAT) designation; Phase 3 clinical trial under development and subject to finalization with FDA
Gene therapies	OCU400 ** AAV-hNR2E3	Gene mutation-associated retinal degeneration*	
		NR2E3 Mutation (RP)	Phase 1/2
		RHO Mutation (RP)	Phase 1/2
		CEP290 Mutation (LCA)	Phase 1/2
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)**	IND planned for Q2
	OCU410ST AAV-hRORA	Stargardt (orphan disease)	IND planned for Q2
Biologicals	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	IND planned for Q1
		Diabetic Retinopathy	IND enabling
		Wet Age-Related Macular Degeneration (Wet AMD)	IND enabling

\*No approved therapies exist

<https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment> | <https://www.aao.org/eye-health/diseases/amd-treatment>

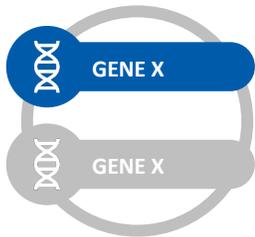
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# Corporate Executive Summary

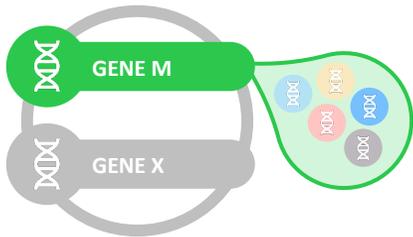
- 1 > Ocugen has an **exciting and unique portfolio** spanning ocular gene therapies, a novel biologic, an orthopedic regenerative cell therapy, and COVID-19 vaccines.
- 2 > We believe the **modifier gene therapy platform** assets (OCU400 and OCU410) are the **most significant drivers of value**. We believe each asset has the potential to be **significant** if clinical data and commercial assumptions are positive—more conservative estimates still offer a meaningful valuation upside.
- 3 > Ocugen will need to **carefully manage available capital** in the near-term to maximize value for the ocular gene therapies. Additional **capital raises and partnerships** will be required to extend the runway and accelerate the portfolio.
- 4 > Investments through **business development** in capability building and portfolio diversification will be important to enable the current portfolio and scale the portfolio in the longer-term.

# Modifier Gene Therapy Platform—Compelling Value Proposition with Potential to Meaningfully Disrupt the Market



**Traditional single-gene augmentation** transfers a functional version of a non-functional gene into target cells

- This approach is limited by its ability to address one gene mutation at a time, meaning ability to address large populations is **significantly constrained**



**Ocugen's modifier gene therapy platform** is designed to introduce a functional gene to modify the expression of many genes/gene networks

- This approach has the **potential to address significantly larger patient populations** in a much shorter period, given streamlined clinical development and regulatory filings

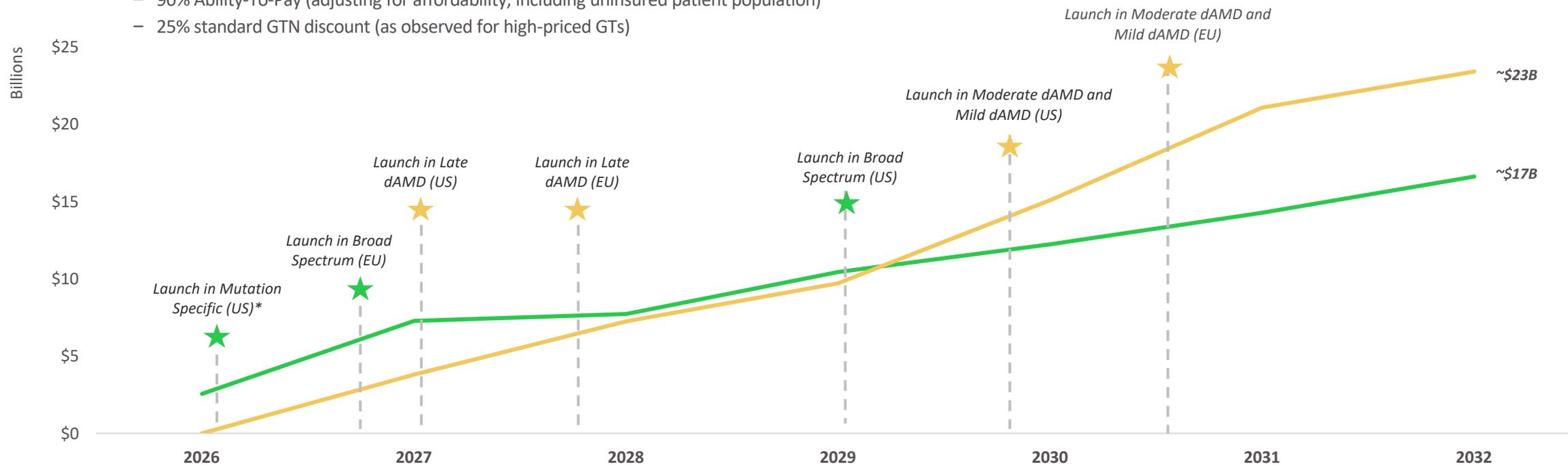
*We believe clinical success of the Modifier Gene Therapy platform will unlock the revenue potential of OCU400 and OCU410 and provide significant valuation upside to Ocugen*

# Potential Market Opportunity for Ocugen Gene Therapies—Revenue Potential of up to ~\$40B in 2032

## Forecasted Net Revenue (OCU400, OCU410)

### Key Assumptions

- 90% Ability-To-Pay (adjusting for affordability, including uninsured patient population)
- 25% standard GTN discount (as observed for high-priced GTs)



### # Doses (in Thousands)\*

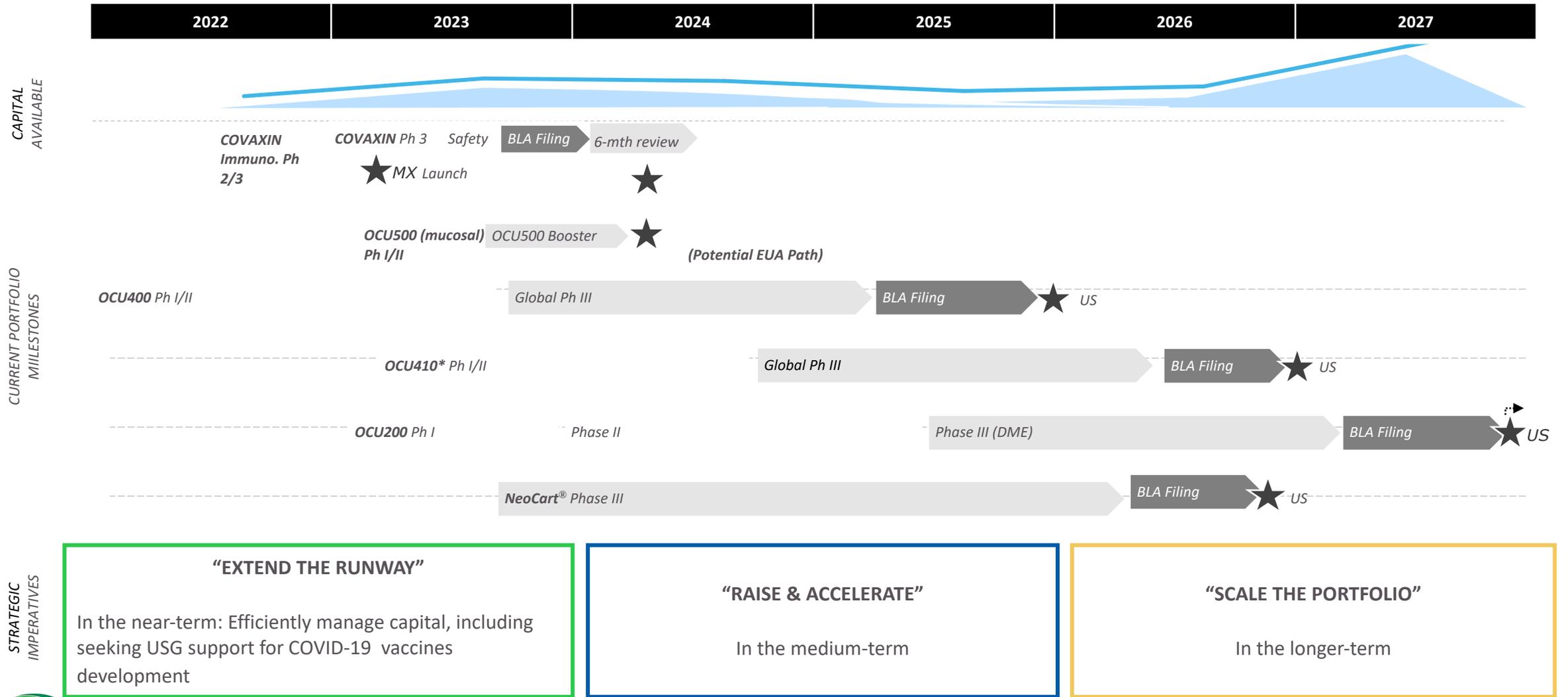
<b>OCU400</b>	6.0	18.6	19.8	25.5	29.4	34.1	39.5
<b>OCU410</b>	-	11.7	24.1	32.1	50.2	71.5	79.3



\*Not risk-adjusted

\*\* Disease prevalence: U.S./EU/UK RP/LCA > 250,000. U.S./EU/UK dAMD (Geographic Atrophy) > 2 million .

# Key Potential Milestones for Portfolio Assets



# Ocugen™ Vision

Fully integrated, patient-centric biotech company focused on vaccines in support of public health and gene and cell therapies targeting unmet medical needs through **Courageous Innovation**





# Modifier Gene Therapy Technology For Retinal Diseases

Arun Upadhyay, PhD  
CSO

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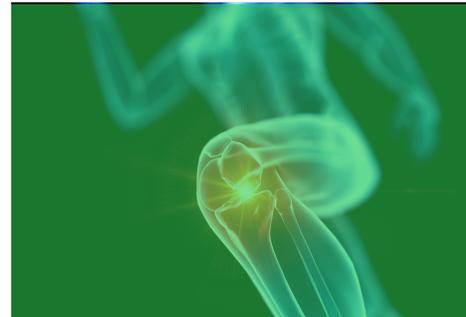
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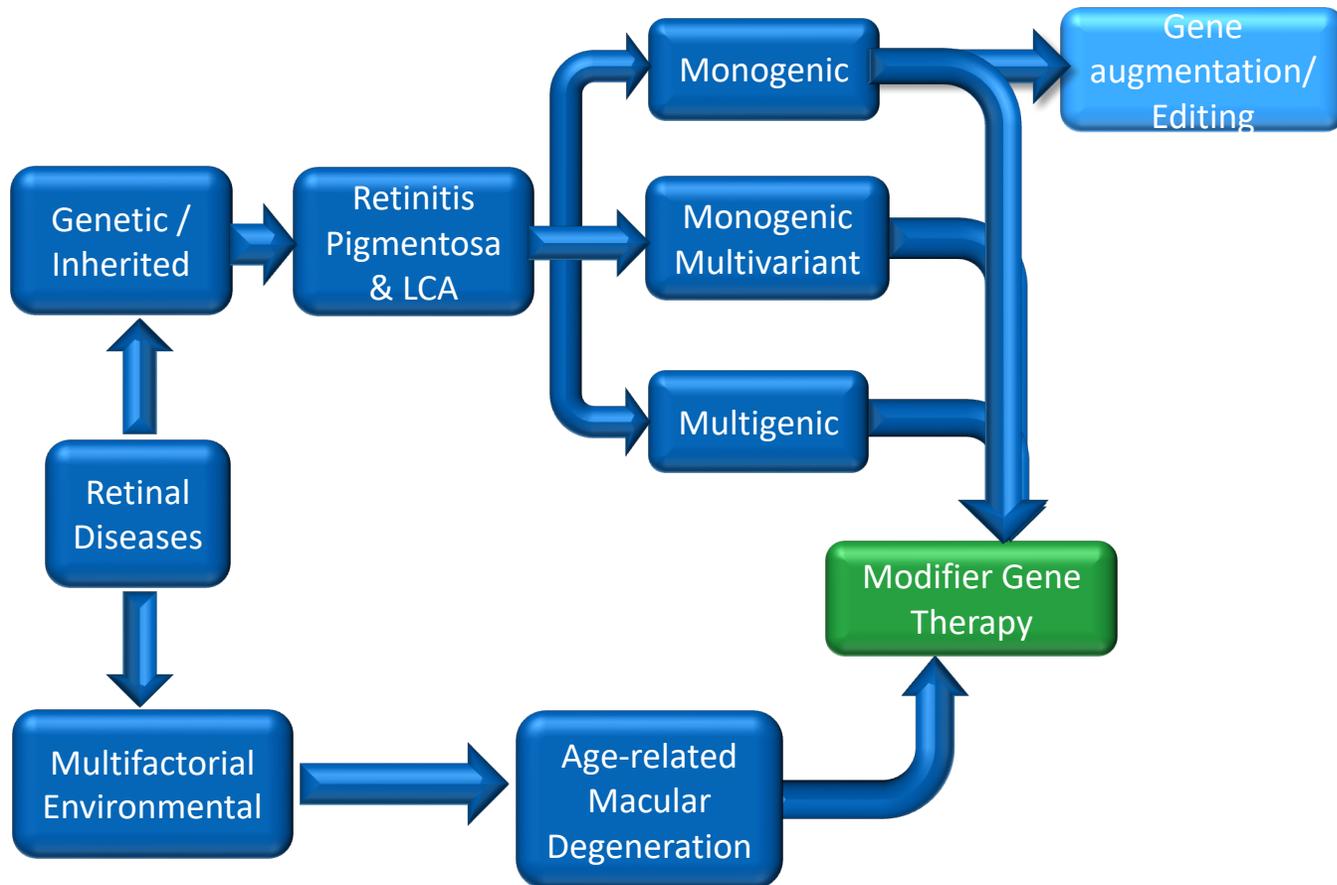


**Developing vaccines** to provide choice to Americans in the fight against **COVID-19**



**Pursuing Regenerative Cell Therapy** to treat serious conditions like articular cartilage lesions

# Why is Modifier Gene Therapy Needed?



## Retinal Diseases

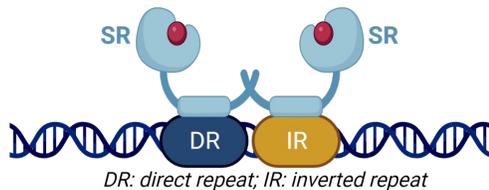
- > IRDs and AMD are most common cause of vision impairment and blindness
- > Can be broadly categorized into monogenic and complex (multifactorial) forms
- > High genetic heterogeneity significantly limits gene-specific therapeutic strategy
  - Monogenic inherited retinal diseases—Retinitis pigmentosa (RP), Leber congenital amaurosis (LCA), and others
- > Gene specific strategy may not be applicable for multifactorial diseases, such as dry age-related macular degeneration
- > Need for mutation-independent approach
  - Modulating key retinal gene-network involved in retinal damage

# Nuclear Hormone Receptors as Modifier Genes

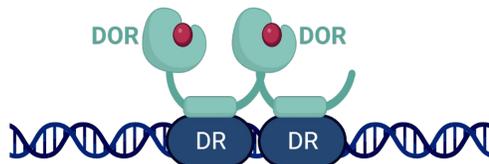
## Classical Endocrine Receptors

AR	RAR $\alpha$
ER $\alpha$	RAR $\beta$
ER $\beta$	RAR $\gamma$
GR	TR $\alpha$
MR	TR $\beta$
PR	VDR

### Class I: Steroid Receptors (SR)



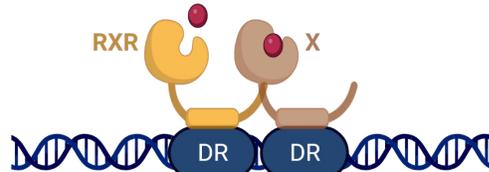
### Class III: Dimeric Orphan Receptors (DOR)



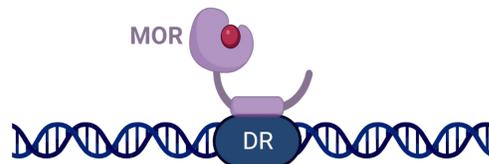
## Adopted and Orphan Receptors

FXR	RXR $\alpha$	ERR $\alpha$	<b>ROR<math>\alpha</math></b>	COUPTF $\alpha$	LRH-1
LXR $\alpha$	RXR $\beta$	ERR $\beta$	ROR $\beta$	COUPTF $\beta$	SF-1
LXR $\beta$	RXR $\gamma$	ERR $\gamma$	ROR $\gamma$	COUPTF $\gamma$	SHP
PPAR $\alpha$	GCNF	Rev-erba	CAR	NOR1	DAX-1
PPAR $\beta/\delta$	HNF4 $\alpha$	Rev-erb $\beta$	PXR	NR4A $\alpha$	TR2
PPAR $\gamma$	HNF4 $\gamma$	<b>NR2E3</b>	TLX	NR4A $\beta$	TR4

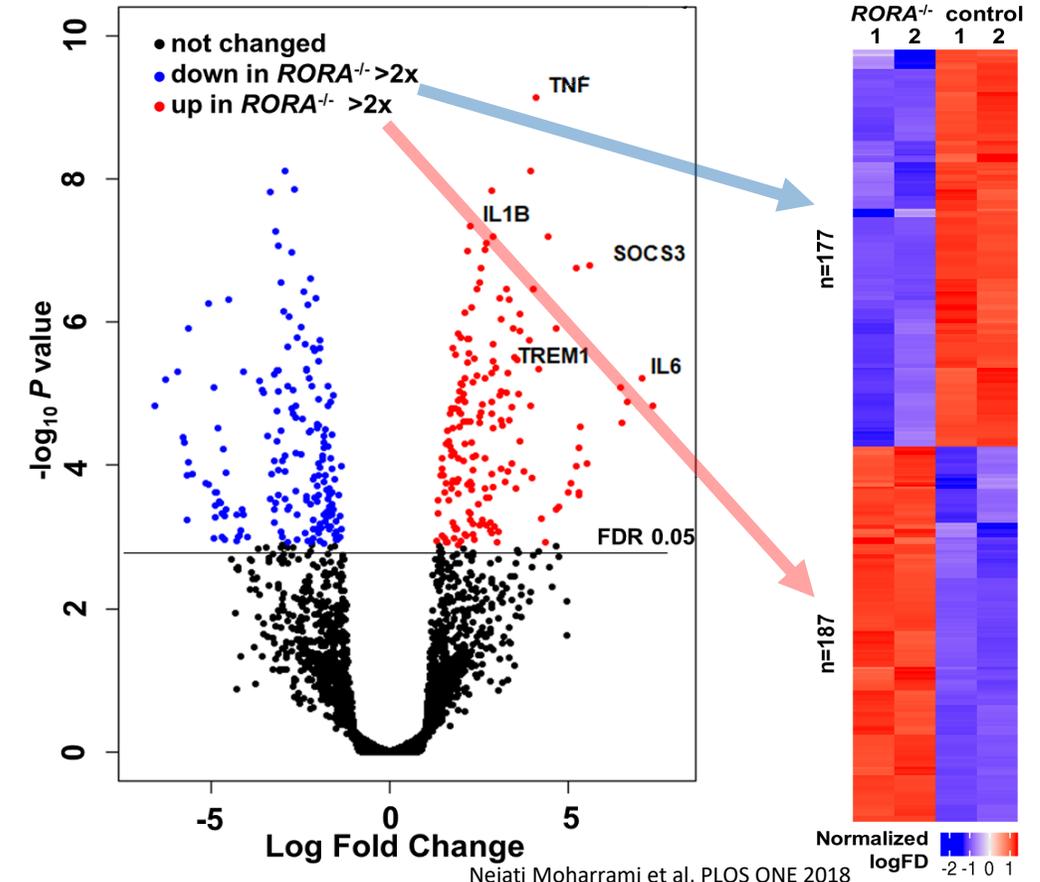
### Class II: Retinoid X Receptor (RXR) Heterodimers



### Class IV: Monomeric Orphan Receptors (MOR)

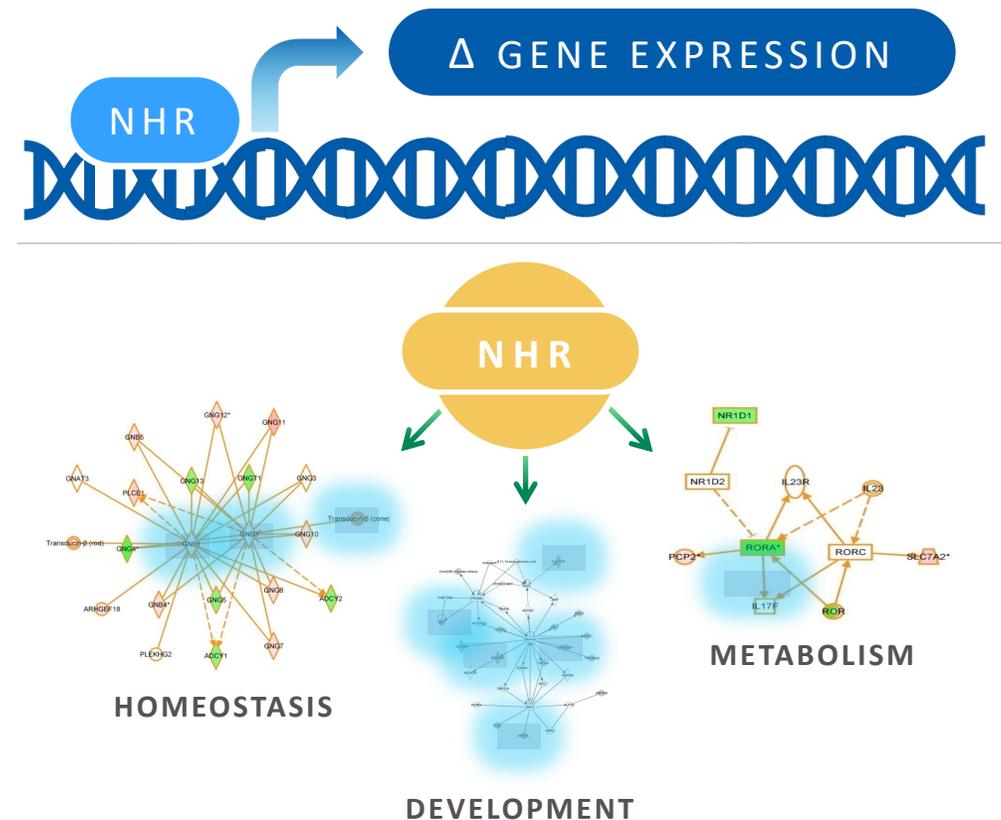


## RORA alone regulates expression of several hundred homeostasis genes



# Why Target Nuclear Hormone Receptor Genes?

- > **Nuclear hormone receptors (NHRs)** are intracellular receptors that **regulate gene expression**
  - NHRs act as “**Master Genes**” inside the cell
- > NHRs can regulate diverse physiological functions
  - Homeostasis
  - Cellular and tissue development
  - Cellular and tissue metabolism
- > The human genome contains 48 NHRs
  - Many have tissue-specific expression patterns
  - NHR dysregulation often leads to disease
    - o Therefore, NHRs are common drug discovery targets



# Pipeline Overview: Modifier Gene Therapy Technology

	 ASSET/PROGRAM	 INDICATION	 STATUS
<b>Modifier Gene Therapy Platform</b>	<b>OCU400 **</b>	<b>*Inherited retinal degeneration*</b>	
		<i>NR2E3 Mutation</i>	Phase 1/2
		<i>RHO Mutation</i>	Phase 1/2
		<i>CEP290 Mutation</i>	Phase 1/2 to be initiated
	<b>OCU410</b>	<b>Dry Age-related Macular Degeneration (Dry AMD)*</b>	IND Enabling
<b>OCU410-ST</b>	<b>Stargardt Disease</b>	IND Enabling	

\* No approved therapies exist  
<https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment> | <https://www.aao.org/eye-health/diseases/amd-treatment>



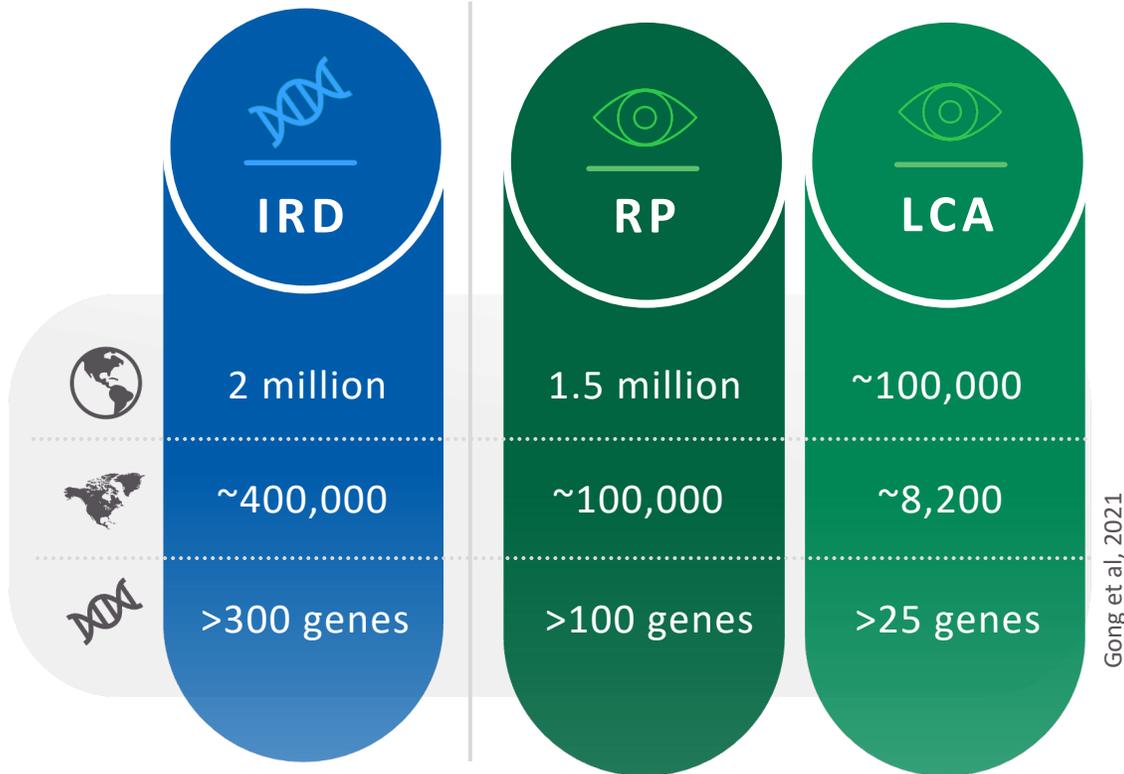
\*\*Orphan drug designation in the US; Broad orphan medicinal product designation by the EC for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)



# Modifier Gene Therapy Platform: OCU400

(AAV5-hNR2E3) for RP and LCA Diseases

# Inherited Retinal Diseases: Prevalence and Associated Genes



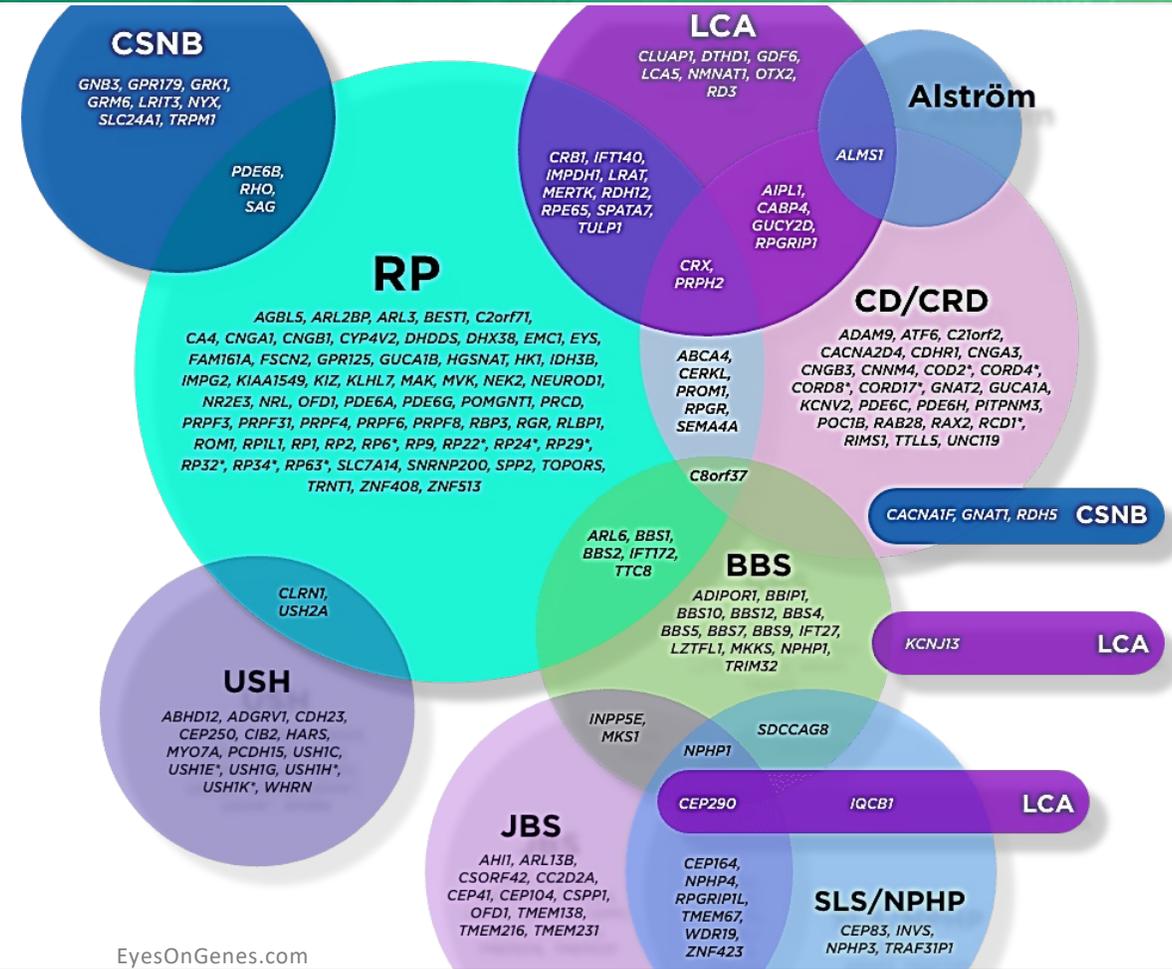
## IRDs: Diverse disease class with large phenotypic and genetic heterogeneity

- > A common cause of irreversible blindness due to retinal cell degeneration
- > Symptom onset can range from birth to adulthood
- > Varying rate of progression and severity
- > Limited information on disease natural history and windows of opportunities for therapeutic intervention
- > RP and LCA are the most common IRDs involving photoreceptors and the retinal pigment epithelium (RPE)
- > RP alone is associated with mutations in >100 genes

# Inherited Retinal Degeneration: A Broader Reach For OCU400

- > Only one approved gene therapy for LCA associated with RPE65 mutation: Luxturna® (Voretigene Neparvovec-rzyl)
- > Electronic Smart glasses as a low vision aid in patients with RP—IrisVision is a Class I medical device
- > **No disease-modifying therapy options are available for broader IRD-associated mutations**

Gene augmentation or editing can only treat a small fraction of the IRD population, but **OCU400 has the potential to treat a large group of patients with IRDs**

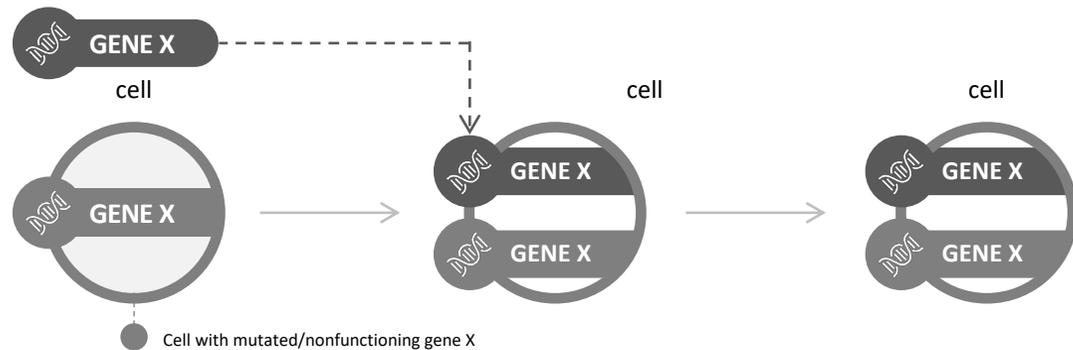


EyesOnGenes.com

# Current Limitations of Conventional Gene Therapy

**Gene Augmentation:** Transfer functional version of a non-functional gene into the target cells.

NORMAL GENE X



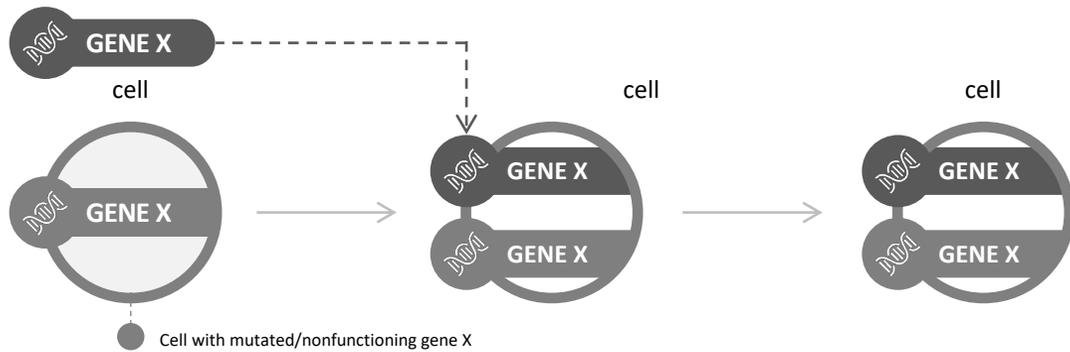
- ➔ Traditional approach that targets one individual gene mutation at a time
- ➔ Regulatory pathway focused on specific product for one disease
- ➔ Longer time to recoup development costs

- > Two patients with the same disease but arising from mutations in different genes cannot benefit from the same gene therapy
  - Example:
    - RP affects 1.5 million people worldwide
    - Associated # of genes exceeds 100
    - **Up to 40% of patients cannot be genetically diagnosed → Difficult to Individualize Treatment**
- > Limited by the capacity of the vehicle
- > Significant costs and effort required to develop and manufacture

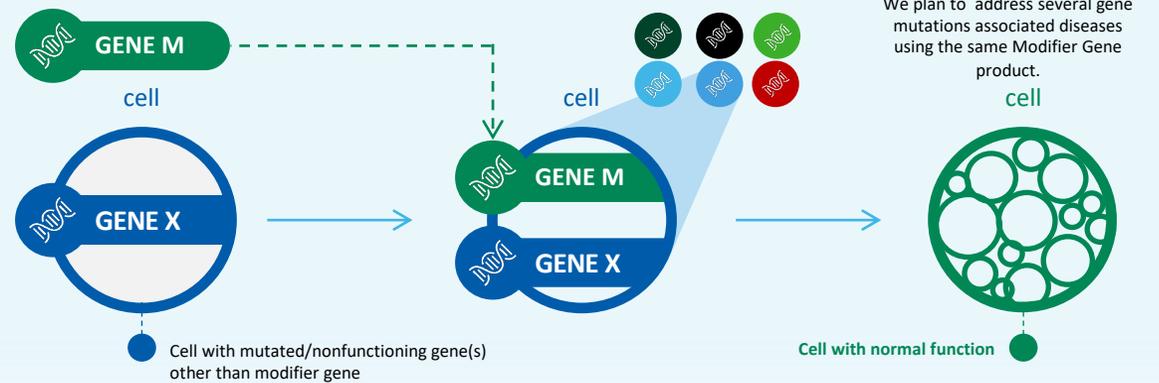
# Modifier Gene Therapy: An Innovative Potential Treatment for IRDs

**Gene Augmentation:** Transfer functional version of a non-functional gene into the target cells.

NORMAL GENE X



**Modifier Gene Therapy:** Designed to introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina.



- OCU400**
- NR2E3 Mutation-Associated Retinal Disease
  - Rhodopsin Mutation-Associated Retinal Disease
  - CEP290 Mutation-Associated Retinal Disease
  - PDE6B Mutation-Associated Retinal Disease

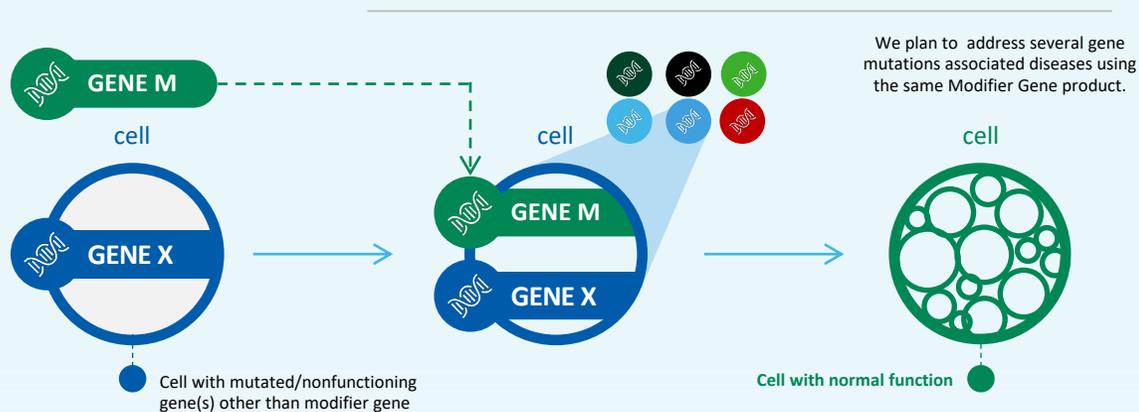
**Broad Spectrum Therapy for RP**

- Traditional approach that targets one individual gene mutation at a time
- Regulatory pathway focused on specific product for one disease
- Longer time to recoup development costs

- Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- Potentially smoother regulatory pathway due to ability to target multiple gene mutations with one product
- Ability to recoup development costs over multiple therapeutic indications

# Modifier Gene Therapy: An Innovative Potential Treatment for IRDs

**Modifier Gene Therapy:** Designed to introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina.



**OCU400**

- *NR2E3* Mutation-Associated Retinal Disease
- *Rhodopsin* Mutation-Associated Retinal Disease
- *CEP290* Mutation-Associated Retinal Disease
- *PDE6B* Mutation-Associated Retinal Disease

**Broad Spectrum Therapy for RP**

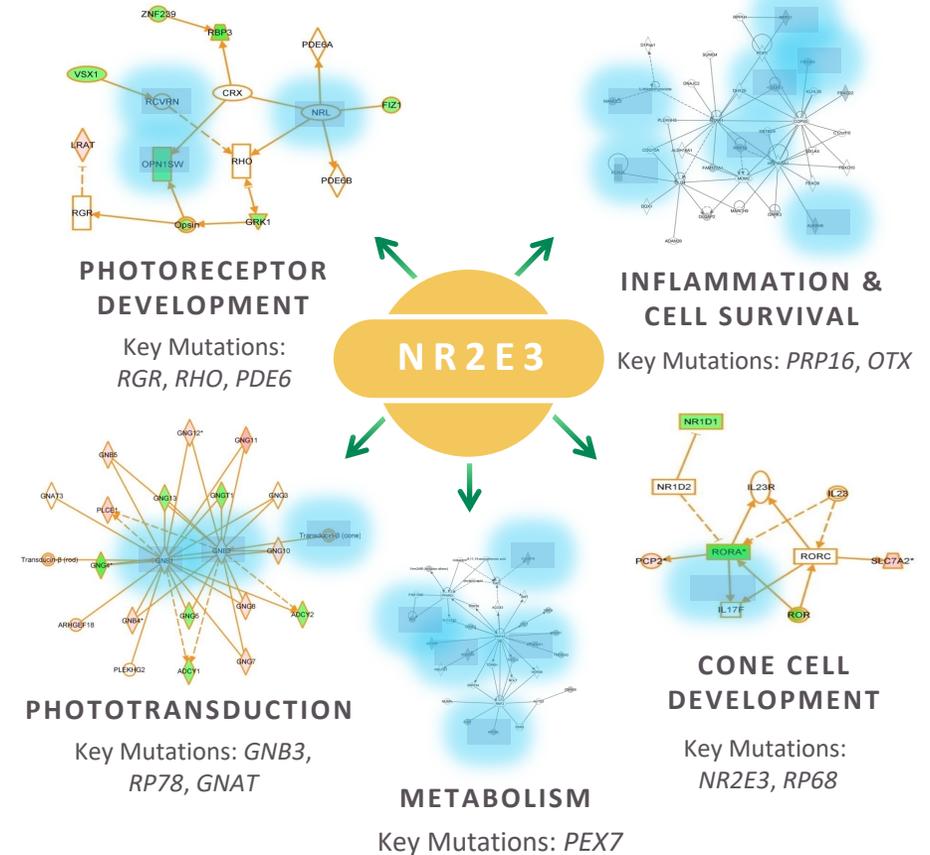
- Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- Potentially smoother regulatory pathway due to ability to target multiple gene mutations with one product
- Ability to recoup development costs over multiple therapeutic indications

- > **Modifier gene therapy: Expression of an upstream “master gene” to affect expression of wide gene-networks downstream**
  - The OCU400 platform delivers a nuclear hormone receptor (NHR) “master gene” *NR2E3* via viral vector
- > **A gene agnostic approach:** Potential for restoring retinal integrity and function across a range of IRD-related genotypes

**Potential to address multiple genetic defects in patients with IRDs using a single product**

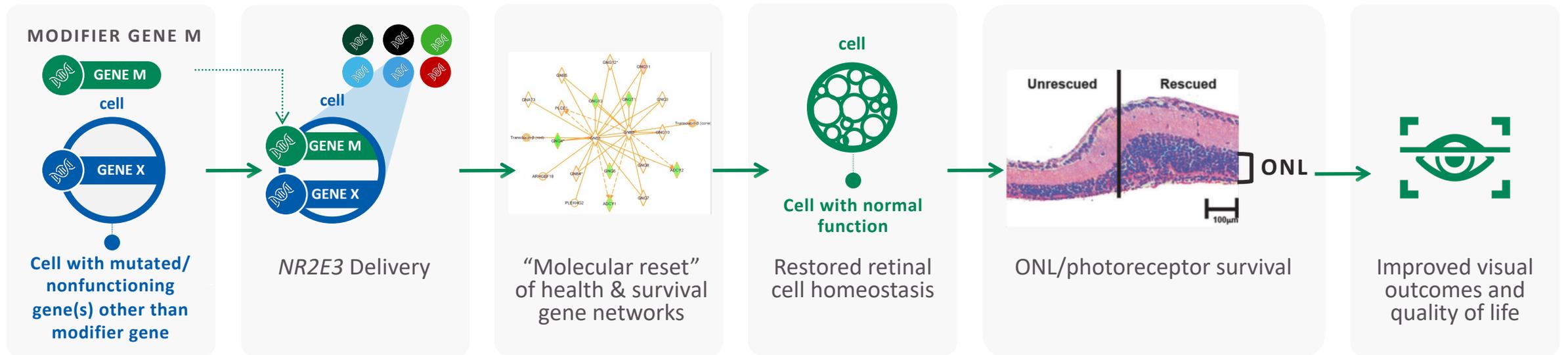
# OCU400 Targets the Retina-specific NHR Gene *NR2E3* to Potentially Treat IRDs

- > Why target the NHR gene *NR2E3*?
  - **NR2E3 is a retina-specific NHR**
    - o Act as a retinal “master gene”
    - o **Regulates:**
      - o **Retinal cell homeostasis** (eg, cell maintenance and survival)
      - o **Metabolism**
      - o **Visual cycle function**



# Modifier Gene Therapy: A Broader Reach

Gene modifier therapy can potentially address multiple genetic defects with a single product.  
In patients with IRDs, this could mean:



# OCU400 Pre-clinical Data: Efficacy Across Multiple RP Mouse Models

5 RP mouse models treated subretinally with OCU400

1

*rd1*

(PDE6 $\beta$ -  
associated RP)

2&3

*Rho*<sup>-/-</sup>  
and *Rho*<sup>P23H</sup>

(both rhodopsin-  
associated RPs)

4

*rd16*

(Leber Congenital  
Amaurosis)

5

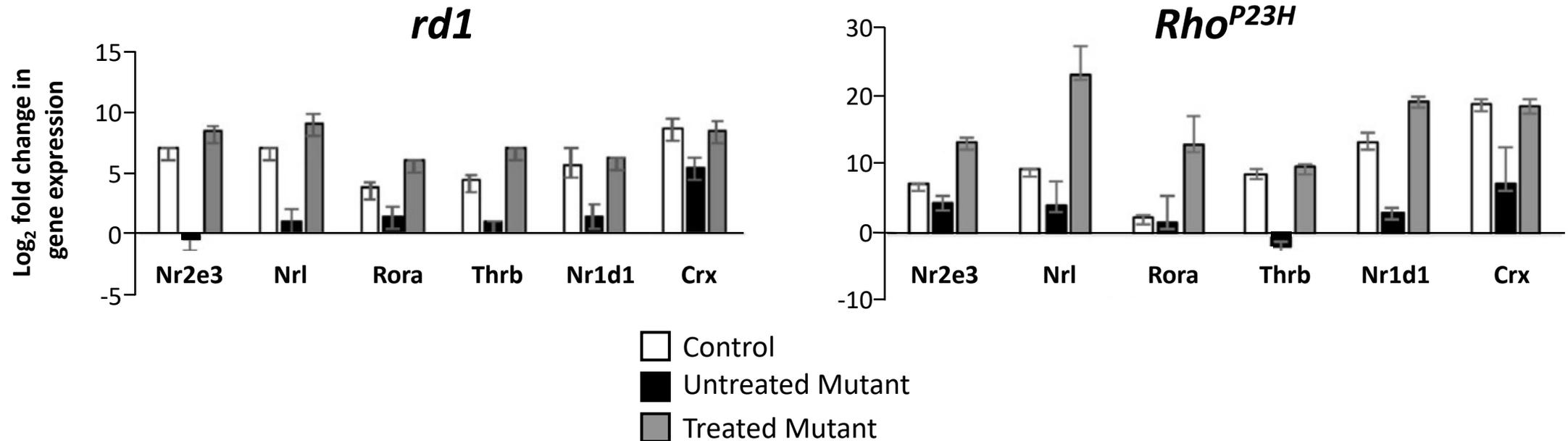
*rd7*

(Enhanced S-cone  
Syndrome)

# OCU400 Pre-clinical Data: *NR2E3* Overexpression Restores Expression of Key Retinal Transcription Factors

***NR2E3* overexpression results in a “molecular reset”**

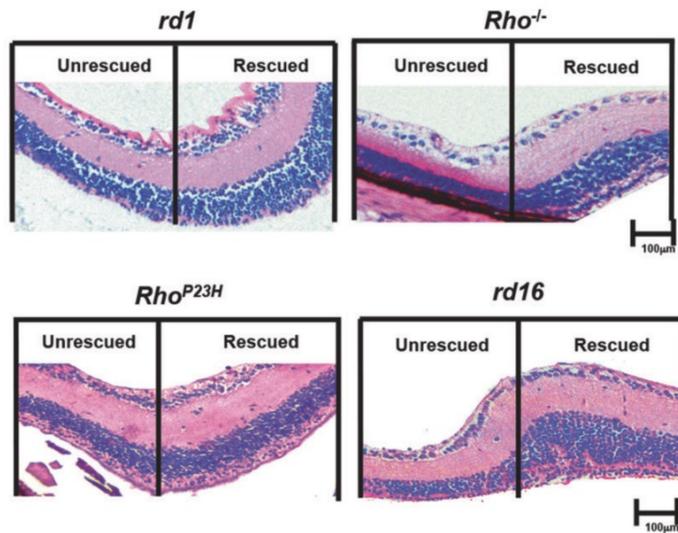
- > Restoration of pro-survival and pro-maintenance genes
- > Recruitment of transcription factors



Untreated *rd1* mutant mice were assessed at P7; untreated *Rho<sup>P23H</sup>* mutant mice were assessed at 1M.  
Treated mutant mice were assessed at 1M.  
Li S. *Gene Ther.* 2021;28(5):223-241.

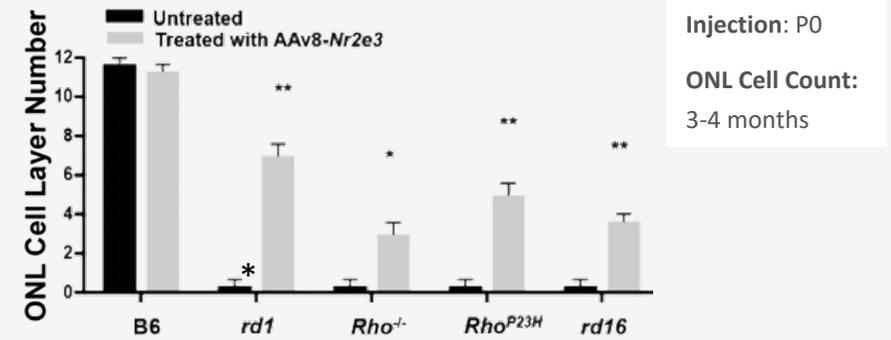
# OCU400 Pre-clinical Data: Rescue of Retinal Cell Counts in Early and Advanced Stage Disease

## OUTER NUCLEAR LAYER (ONL) STAINING

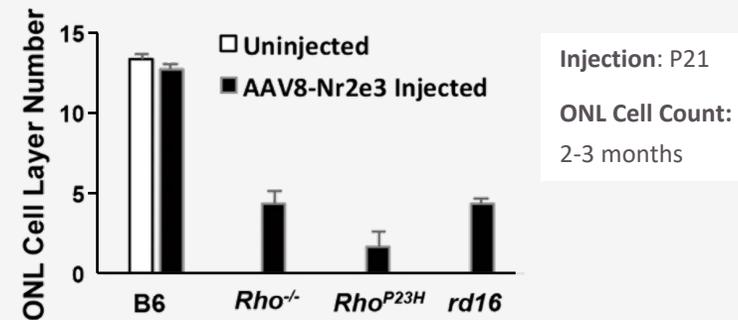


OCU400 helps preserve retinal cells, such as photoreceptors, which could translate to improved retinal health in patients with IRDs

## EARLY STAGE RESCUE



## ADVANCED STAGE RESCUE

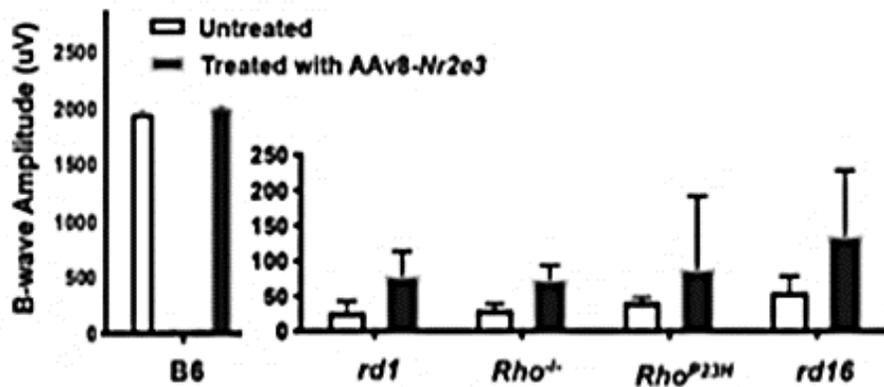


# OCU400 Pre-clinical Data: Improved ERG Signals



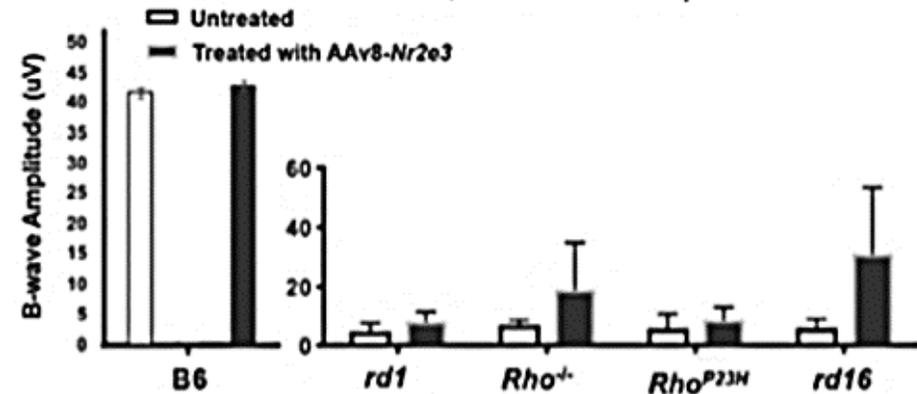
## SCOTOPIC: ROD-FOCUSED

### ERG B-WAVE AMPLITUDE



## PHOTOPIC: CONE-FOCUSED

### ERG B-WAVE AMPLITUDE

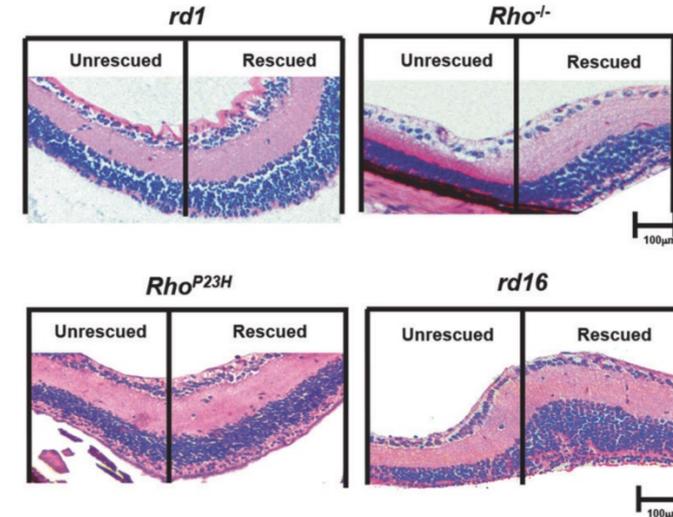


OCU400 enhances the retina's electrical activity, which could mean improved vision for patients with IRDs

# OCU400: Clinical Opportunities Backed by Pre-clinical Science

- > OCU400 causes overexpression of the retina-specific “master gene” (ie, NHR) *NR2E3*
  - Viral vector-mediated delivery of functional *NR2E3* to the retina
- > In IRDs like RP, mutations can disrupt gene expression homeostasis
  - *NR2E3* regulates the expression of whole gene networks involved in retinal maintenance, resulting in
    - o Increased expression of pro-cell health and maintenance transcription factors
    - o Improved ONL morphology in **early and advanced disease**
    - o Rescued retina function (ERG response)

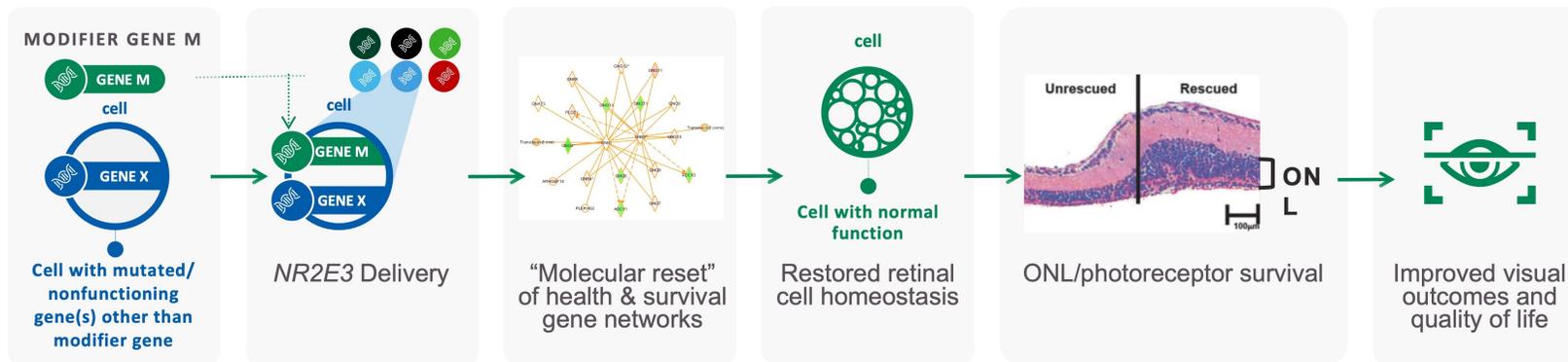
## OUTER NUCLEAR LAYER (ONL) STAINING



***NR2E3* overexpression can benefit RP disease state across multiple genotypes**

# Modifier Gene Therapy: A Broader Reach

Our pre-clinical data show that OCU400 could produce important anatomical and *clinical* benefits for patients with IRDs



## POTENTIAL PATIENT OUTCOMES

Maintained retinal health to **delay or prevent disease progression**

Patient anatomical and potentially **functional benefit in both early or advanced disease stage**

**Prolonged visual function** for

- Keeping an independent lifestyle
- Improved quality of life

# OCU400 Developmental Stage and Regulatory Milestones

## PHASE 1/2

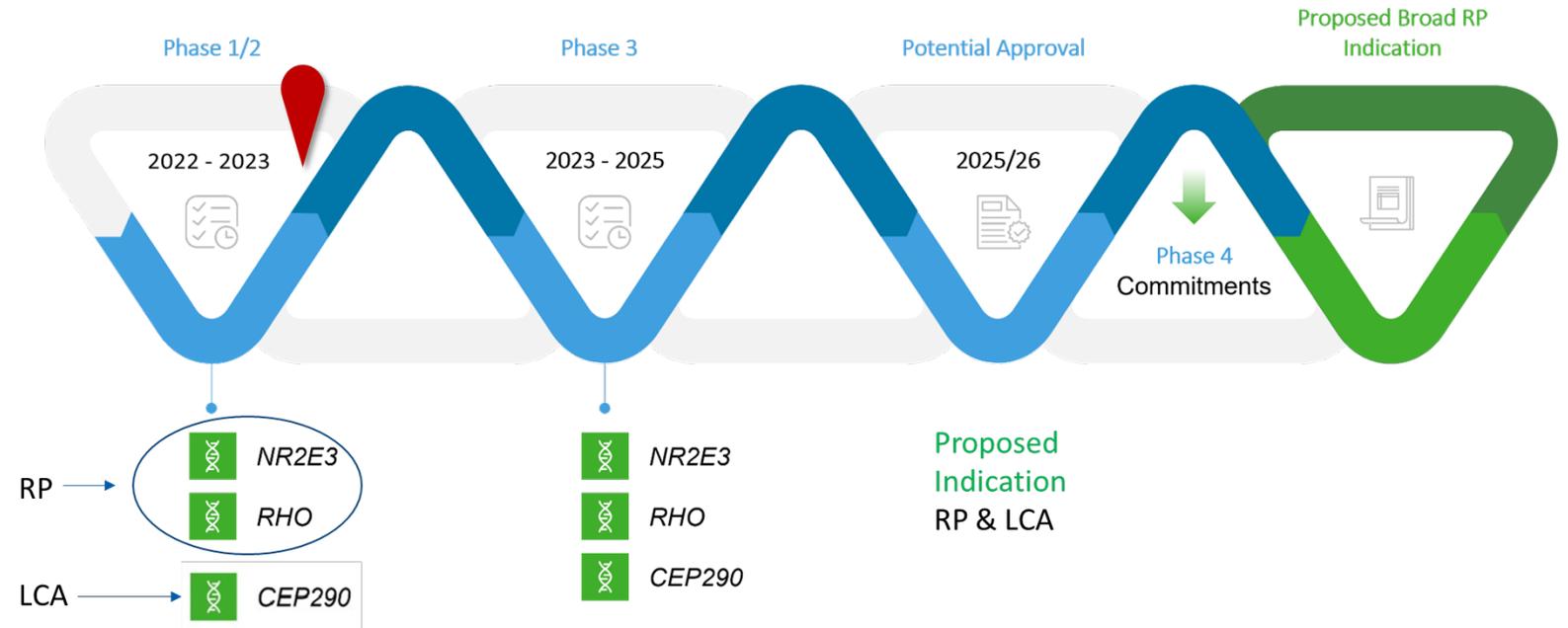
Dose escalation in *NR2E3* and *RHO* patients

Expansion to include *CEP290* patients

- > Orphan Drug Designations for *NR2E3*, *RHO*, *PDE6B* and *CEP290* mutations associated IRDs (FDA)

- Ocugen is also considering broader use of the platform

- > Orphan Medicinal Product Designation from EMA for the treatment of RP and LCA

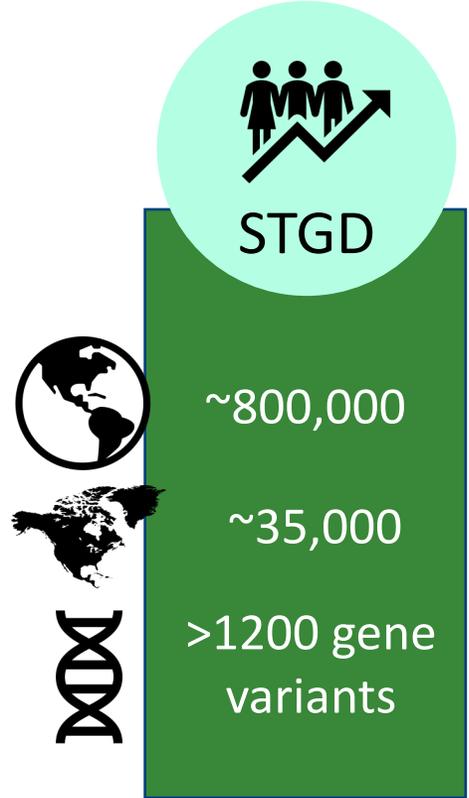
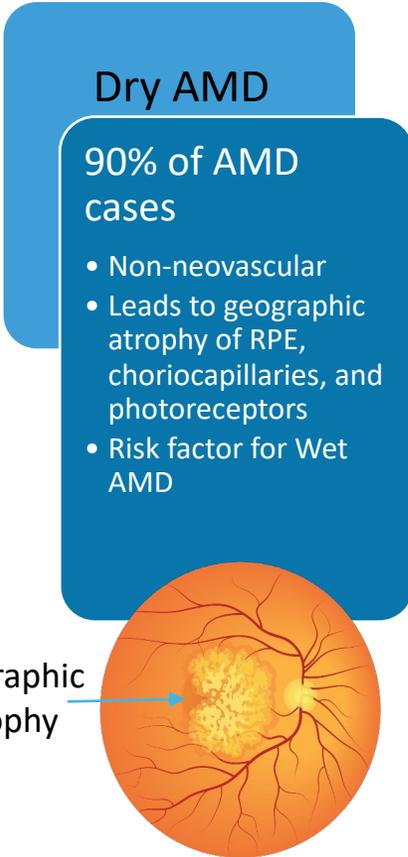
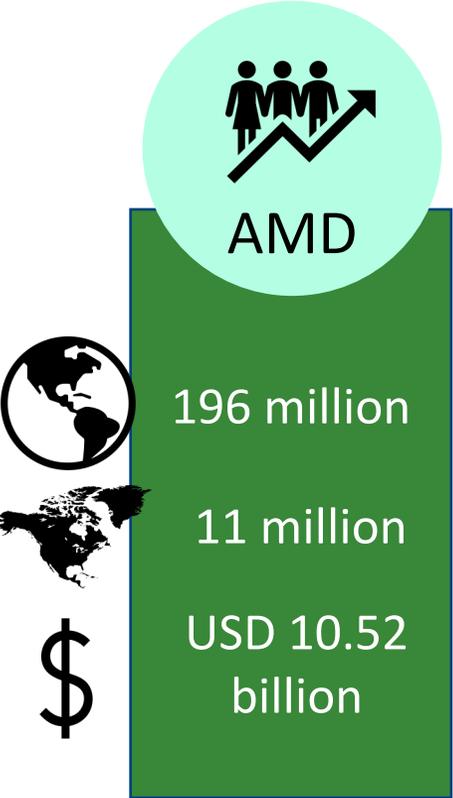




# Modifier Gene Therapy Platform: OCU410 & OCU410-ST

AAV5-*hRORA* for Dry AMD and Stargardt Diseases

# Age-related Macular Degeneration (AMD) and Stargardt Disease: Prevalence



# Age-related Macular Degeneration (AMD) Stargardt Disease (STGD)



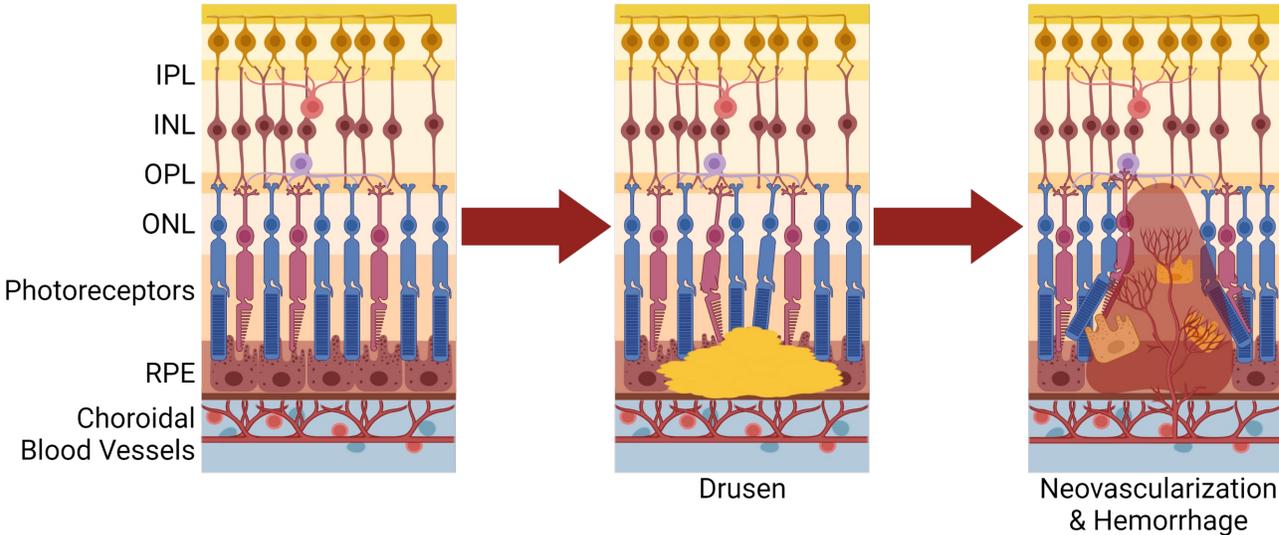
Healthy Retina



Dry AMD



Wet AMD



## Macular Degeneration

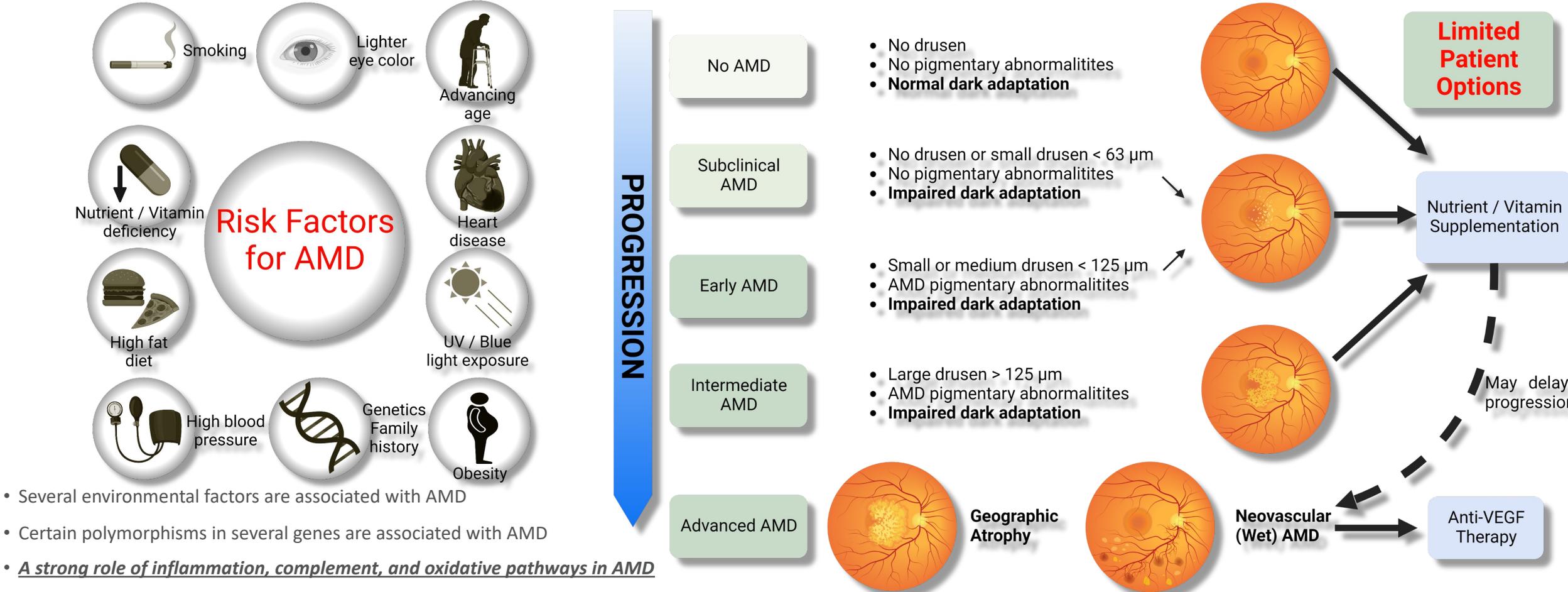
Acquired Age-related

Inherited

- ❖ AMD starts as a “dry,” non-neovascular form
- ❖ Progresses to geographic atrophy
- ❖ Most prevalent (≈90%) form
- ❖ Can progress to a more rapid “wet,” neovascular form
- ❖ Wet AMD may cause vascular leakage, hemorrhage, and fibrovascular growth

- ❖ Stargardt Disease (STGD1)
  - Dysfunction of ABCA4,
  - >1,200 ABCA4 variants are associated with STGD
  - Important for detoxifying oxidized retinol compounds in visual cycle

# AMD Pathogenesis and *Limited* Treatment Approaches

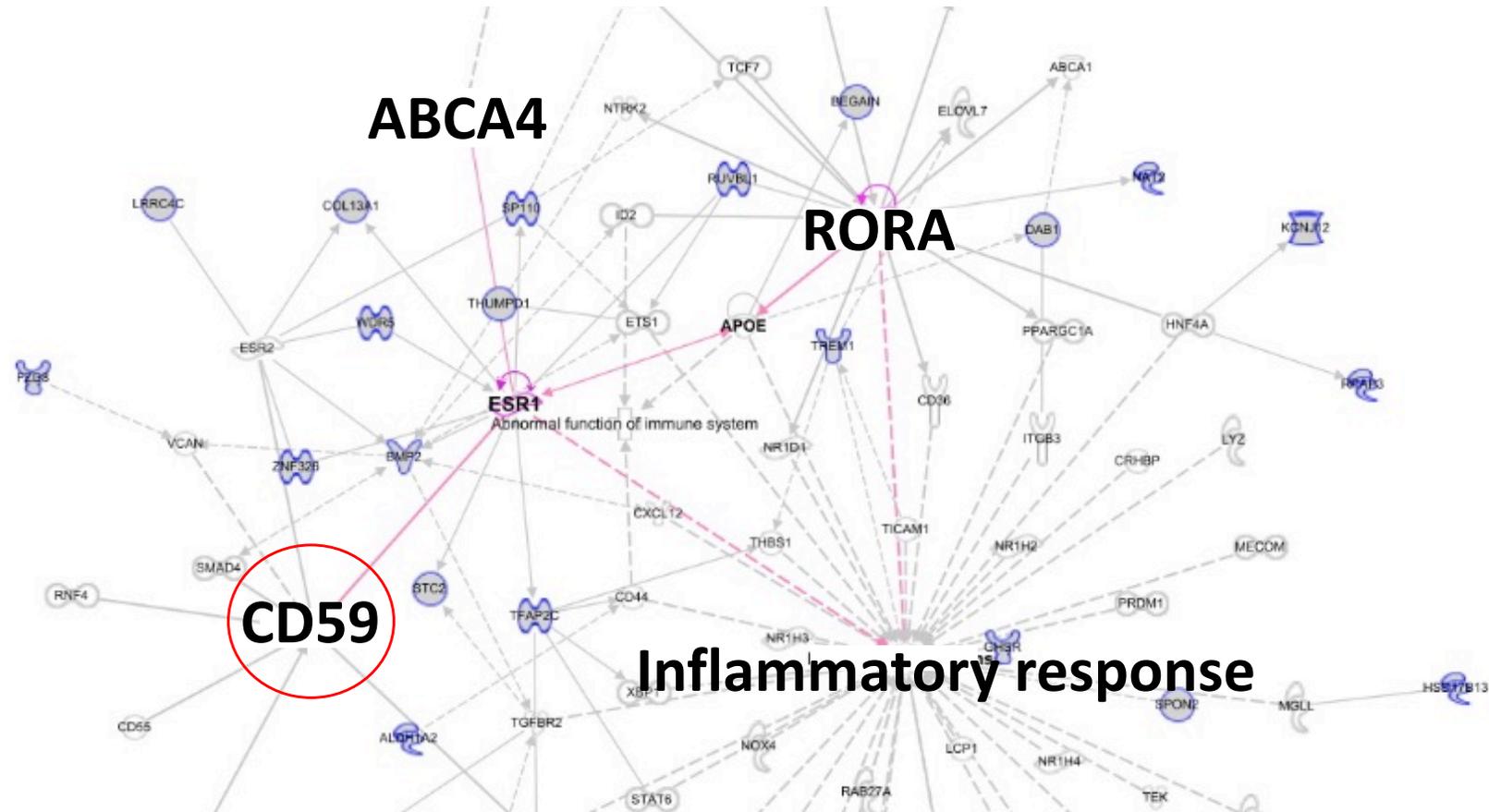


- Several environmental factors are associated with AMD
- Certain polymorphisms in several genes are associated with AMD
- *A strong role of inflammation, complement, and oxidative pathways in AMD*

# RORA regulated gene networks are relevant in AMD and Stargardt disease

Ingenuity Pathway Analysis of Canonical Stargardt Gene Networks show significant overlap with

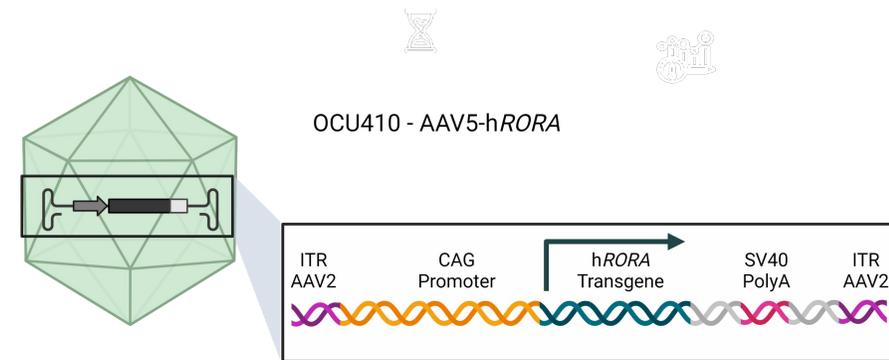
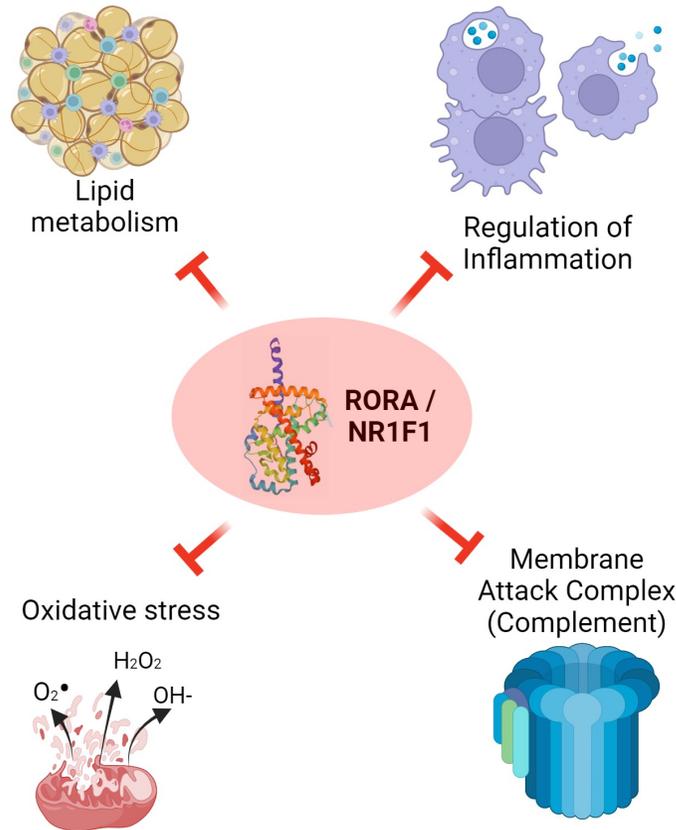
- RORA gene network
- Inflammatory response pathway
- Complement machinery



# OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD

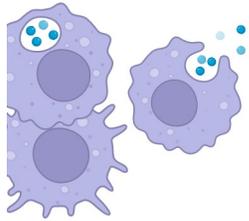
- Reduce oxidative stress
- Limit lipofuscin deposits
- Reduce chronic inflammation
- Improve choroidal blood flow insufficiency

The Retinoic Acid Related (RAR) Orphan Receptor Alpha (**RORA**) regulates several gene networks

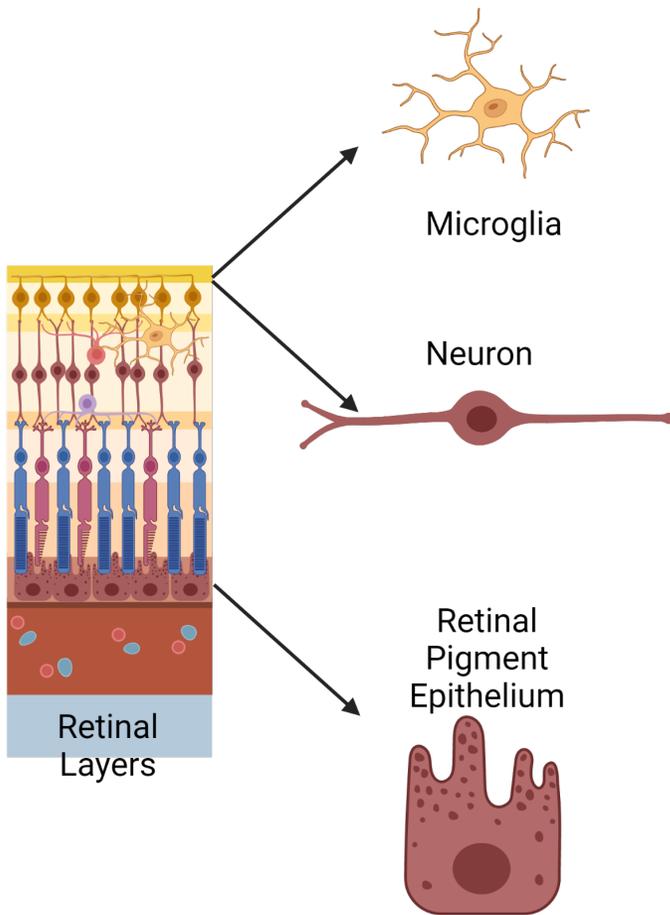


**OCU410 is an adeno-associated virus-based vector containing Human *RORA* (isoform 1)**

# OCU410: Anti-Inflammatory Response

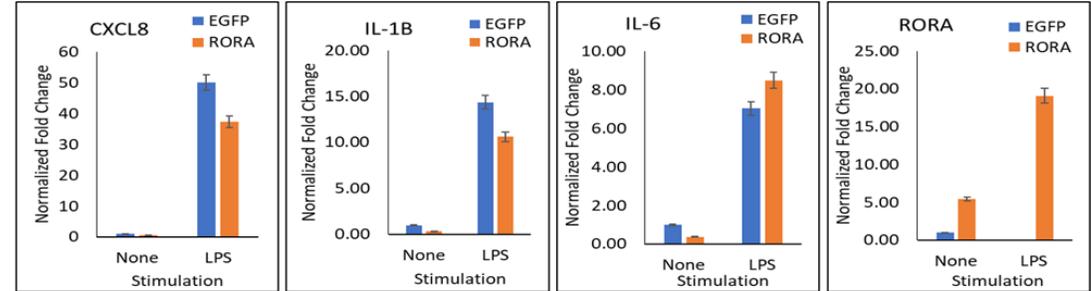


Regulation of Inflammation

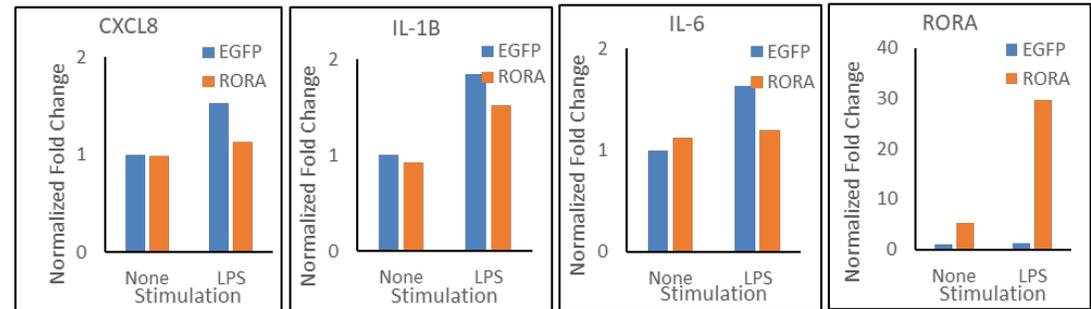


OCU410 suppresses inflammatory response in multiple cell lines

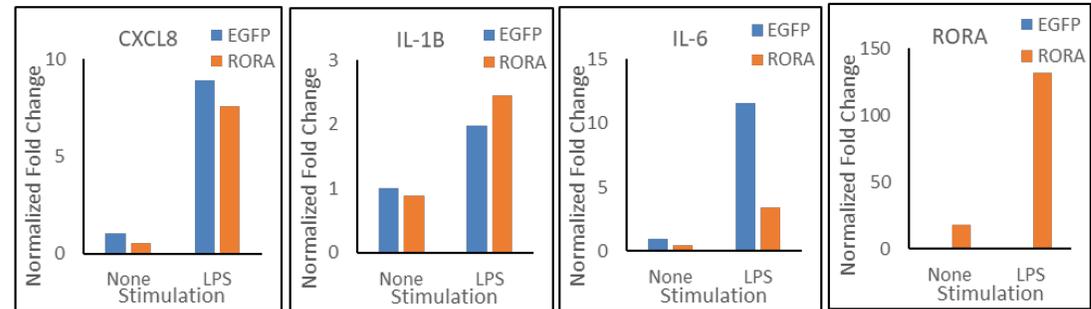
HMC3



U87

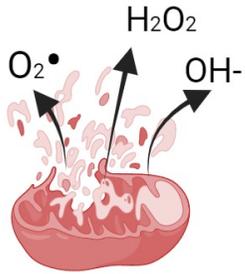


ARPE19

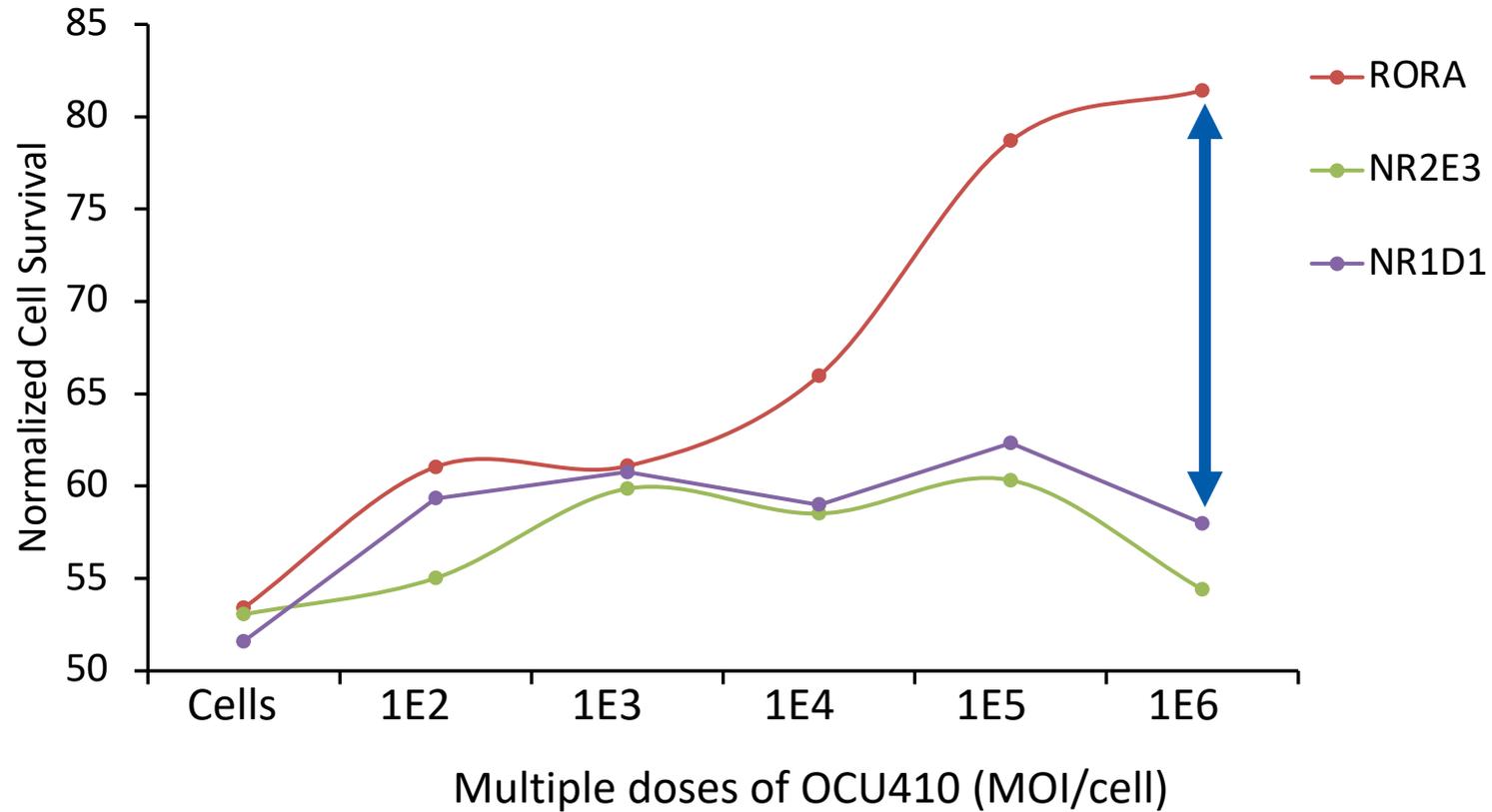


# OCU410 Protects Against Oxidative Stress

Oxidative stress

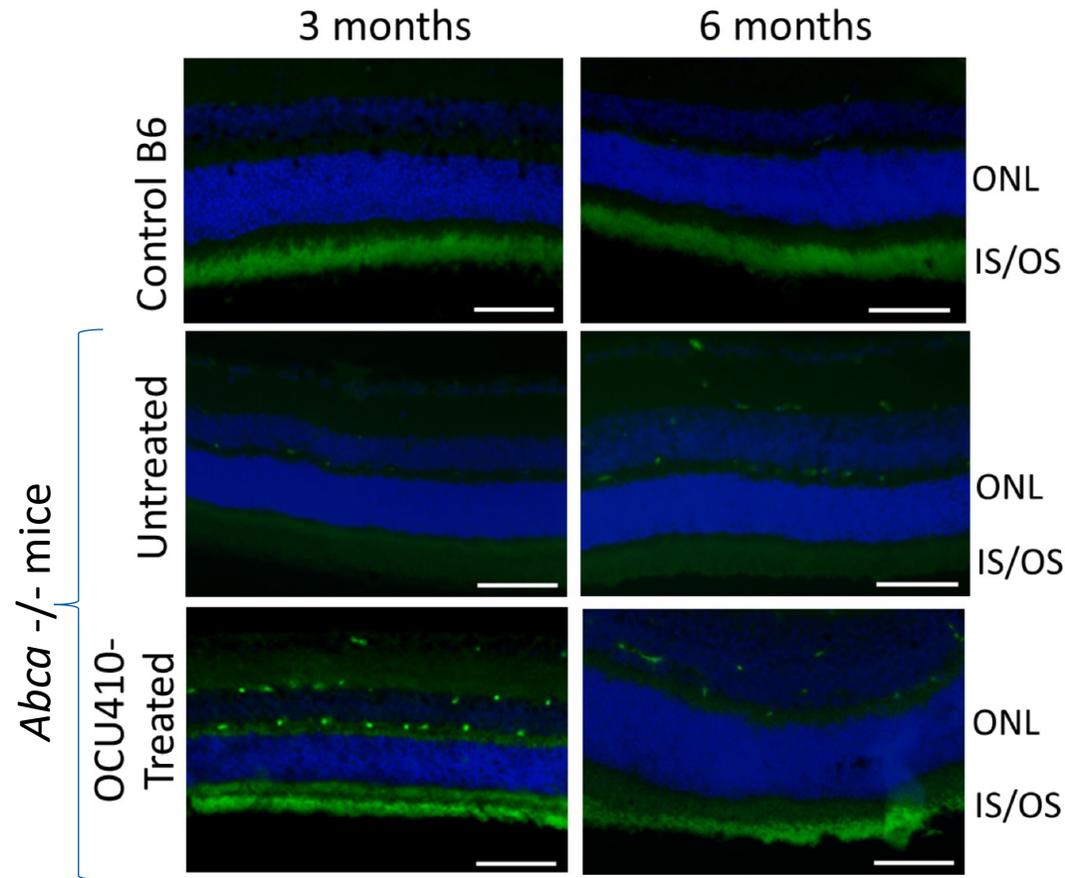


OCU410 Rescues  $NaIO_3$  mediated oxidative death in ARPE19 cells



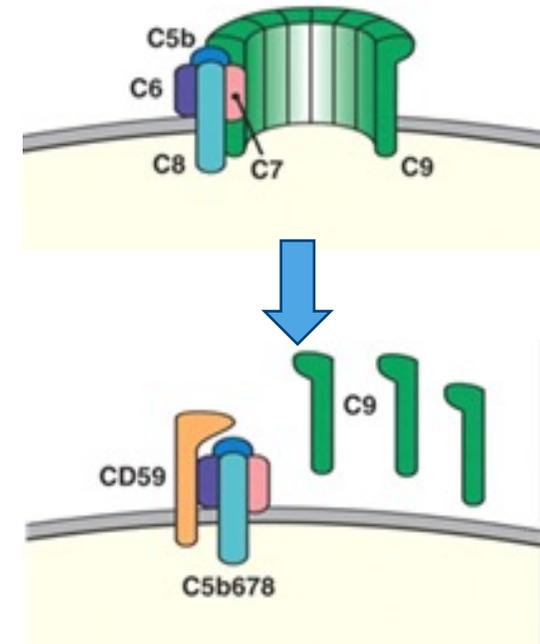
# OCU410 Restores CD59 Expression in ABCA4 -/- Mice

- ABCA4 transports oxidized retinol compounds from photoreceptors to RPE cells for detoxification
- Gene variants of ABCA4 are associated with both Stargardt disease and AMD. *ABCA4* -/- mice show very low CD59 expression in their retinas
- OCU410 CD59 expression in the RPE cells
- CD59 prevents the formation of the complement membrane attack complex (MAC)



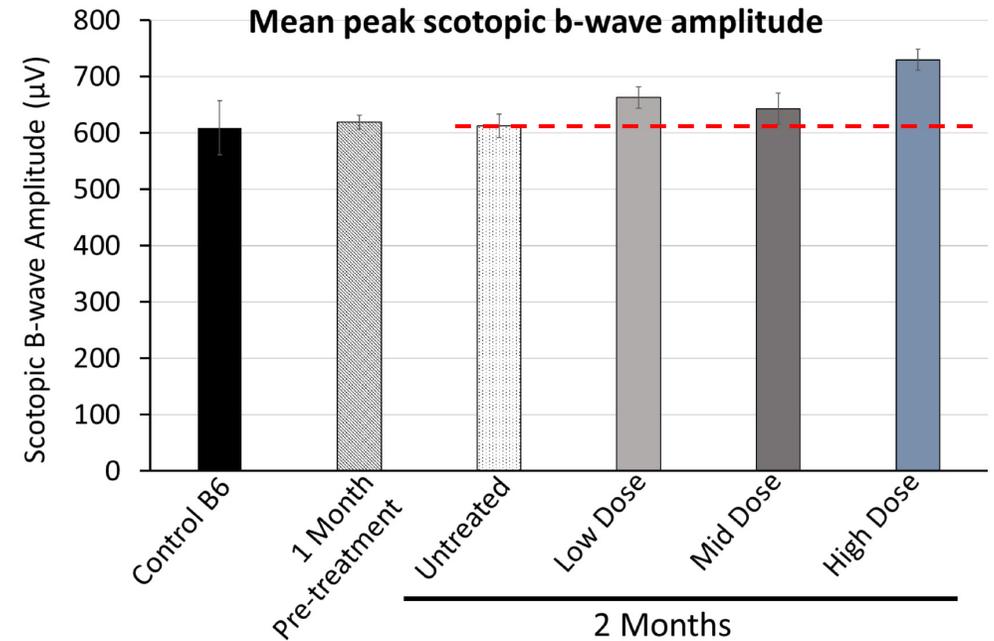
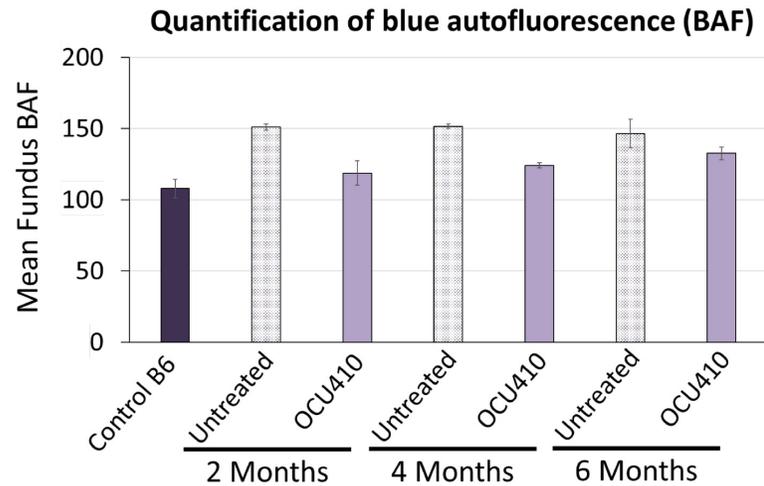
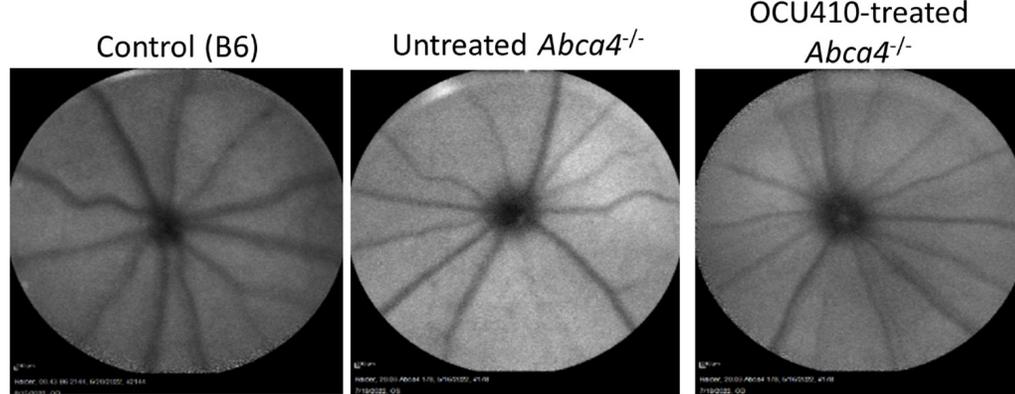
Immunohistochemistry of retina showing CD59 and DAPI

CD59 prevents the formation of the complement membrane attack complex



# OCU410: Restoring Retinal Function in *ABCA4* <sup>-/-</sup> Mice

## Fundus Blue Autofluorescence is restored by OCU410



# OCU410: Summary

- Significant global unmet medical need—more than 176 million of individuals affected with dry AMD with no approved therapy
- Stargardt disease involves >1200 gene variants of ABCA4 gene. Large gene size and number of variants makes gene augmentation/editing therapy difficult
- OCU410 reduced inflammation mediated by suppressing complement and other proinflammatory pathways
- OCU410 plays a role in regulating genes associated with Dry-AMD and Stargardt disease
- OCU410 in vitro and in vivo studies demonstrate its potential favorable role in Dry AMD and Stargardt disease treatment

**Target IND submission Q2 2023 to initiate Phase 1/2 clinical studies for GA and STGD**

# Ocugen™ Vision

Fully integrated, patient-centric biotech company focused on vaccines in support of public health and gene and cell therapies targeting unmet medical needs through **Courageous Innovation**



Thank you!