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): **November 1, 2022**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

11 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701
(Address, including zip code, and telephone number, including area code, of principal executive office)

N/A
(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 (see General Instruction A.2. below):

☐ 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, $0.01 par value per share	OCGN	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

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.

Attached as Exhibits 99.1 and 99.2 hereto and furnished herewith are presentations that Ocugen, Inc. (the "Company") intends to present at its in-person Research & Development Day on November 1, 2022 ("R&D Day").

In addition, attached as Exhibits 99.3, 99.4, 99.5, 99.6, 99.7, and 99.8 hereto and furnished herewith are copies of the poster presentations and displays that the Company intends to use and display throughout R&D Day.

The information disclosed under Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1, 99.2, 99.3, 99.4, 99.5, 99.6, 99.7, and 99.8, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any Company filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being furnished herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Ocugen, Inc. Presentation – Long-Term Outlook.
99.2	Ocugen, Inc. Presentation – Modifier Gene Therapy Technology.
99.3	Poster Presentation (COVAXIN)
99.4	Poster Presentation (Mucosal Vaccine)
99.5	Poster Presentation (OCU400)
99.6	Poster Presentation (OCU410)
99.7	Poster Presentation (OCU200)
99.8	Poster Presentation (NeoCart)
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.

Date: November 1, 2022

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chief Executive Officer and Chairman

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.

In addition, this presentation contains estimates, projections and other information concerning market, industry and other data. We obtained this data from our own internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. These data involve a number of assumptions and limitations, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed in our filings with the SEC. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. While we believe such information is generally reliable, we have not independently verified any third-party information.

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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

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

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

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

ocugen

Pipeline Overview

	Asset/Program	Indication	Current Status
Vaccines	COVAXIN™ (BBV152) SARS-CoV-2 virus	COVID-19	• EUA for adults in Mexico; EUA for 5 to 18-year-olds submitted • Recruitment completed for U.S. Phase 2/3 Immuno-bridging and broadening clinical trial
	OCU500 Mucosal vaccine	COVID-19	• License secured from Washington University • Phase 1/2 pending FDA discussions
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

**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)

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.

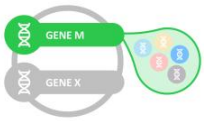
3. Ocugen will need to **carefully manage available capital** in the near-term to maximize value for the ocular gene therapies. Additional **capital raises and partnerships** will be required to extend the runway and accelerate the portfolio.

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

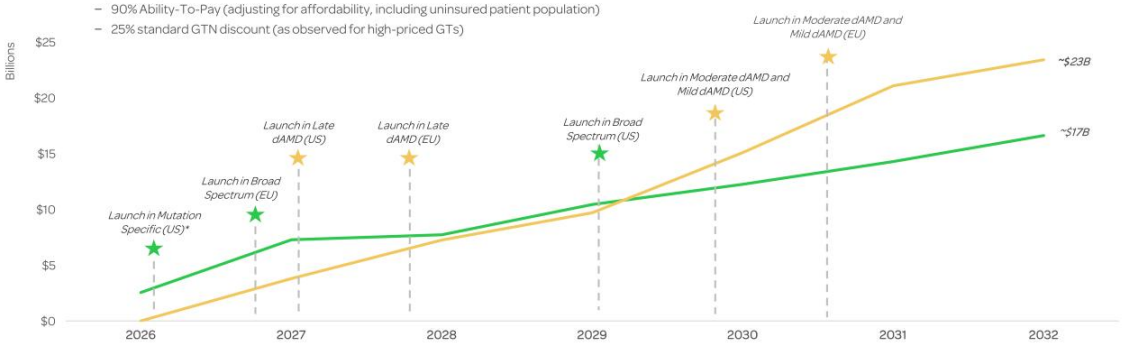
- This approach has the **potential to address significantly larger patient populations** in a much shorter period, given streamlined clinical development and regulatory filings

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)

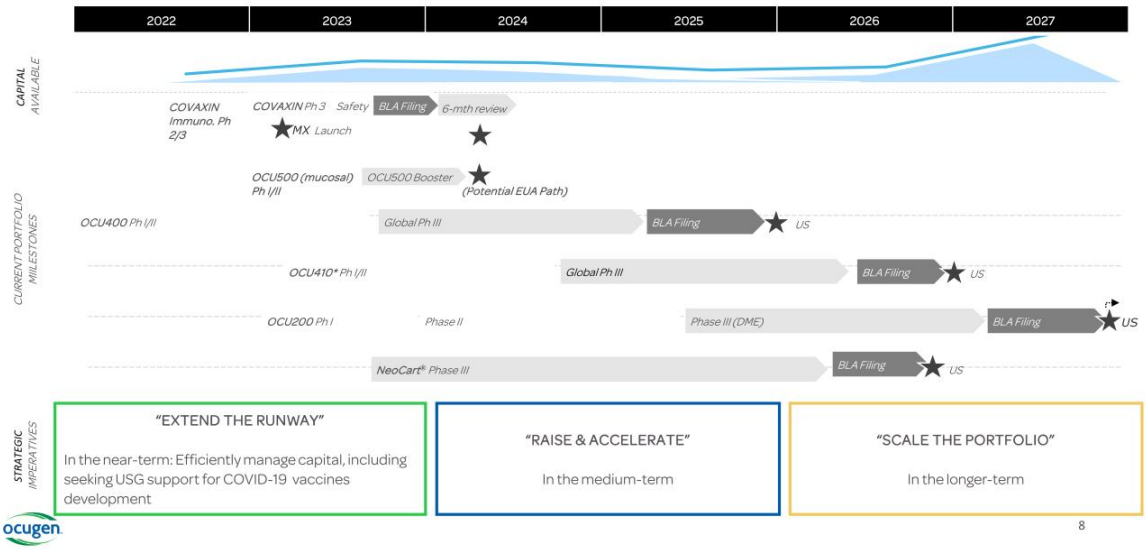


 # Doses *(in Thousands)**

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

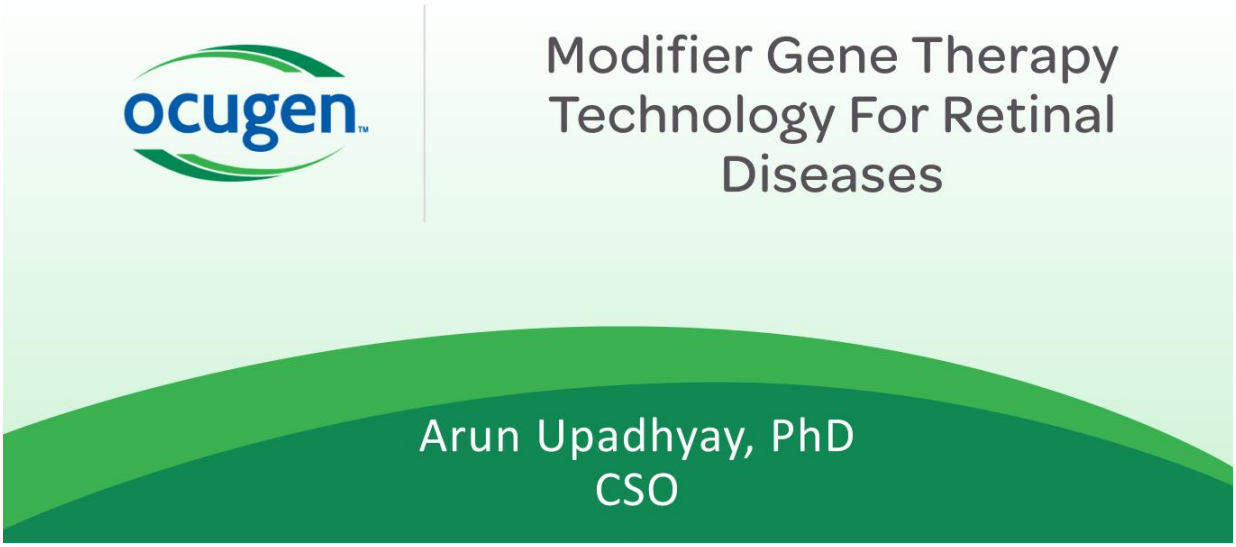
** Not risk-adjusted*
*** Disease prevalence: U.S./EU/UK RP/LCA > 250,000. U.S./EU/UK dAMD (Geographic Atrophy) > 2 million.*

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**


ocugen
Modifier Gene Therapy Technology For Retinal Diseases
Arun Upadhyay, PhD
CSO

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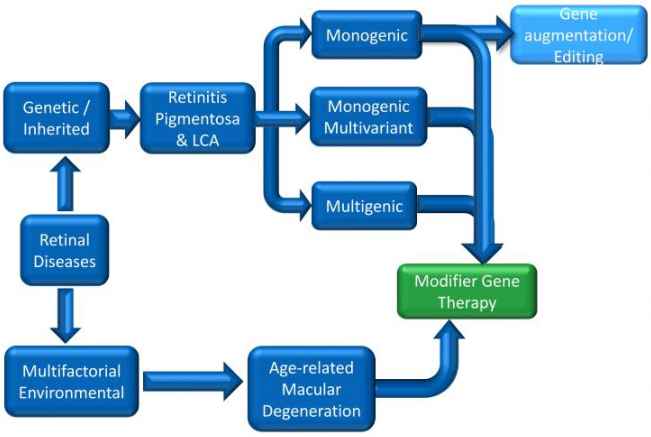
Why is Modifier Gene Therapy Needed?



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

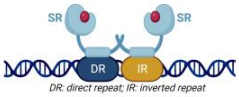
Classical Endocrine Receptors

AR	RARα
ERα	RARβ
ERβ	RARγ
GR	TRα
MR	TRβ
PR	VDR

Adopted and Orphan Receptors

FXR	RXRα	ERRα	RORα	COUPTFα	LRH-1
LXRα	RXRβ	ERRβ	RORβ	COUPTFβ	SF-1
LXRβ	RXRγ	ERRγ	RORγ	COUPTFγ	SHP
PPARα	GCNF	Rev-erbα	CAR	NOR1	DAX-1
PPARβ/δ	HNF4α	Rev-erbβ	PXR	NR4Aα	TR2
PPARγ	HNF4γ	NR2E3	TLX	NR4Aβ	TR4

Class I: Steroid Receptors (SR)



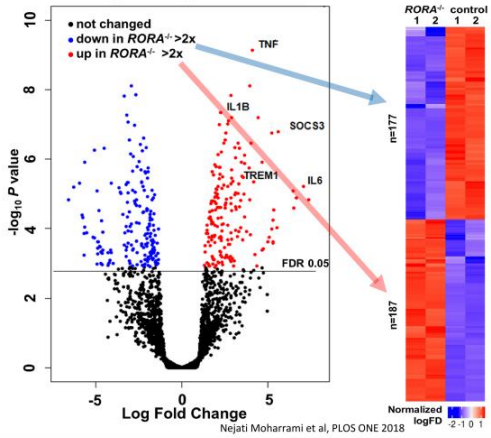
DR: direct repeat; IR: inverted repeat

Class II: Retinoid X Receptor (RXR) Heterodimers

Class III: Dimeric Orphan Receptors (DOR)

Class IV: Monomeric Orphan Receptors (MOR)

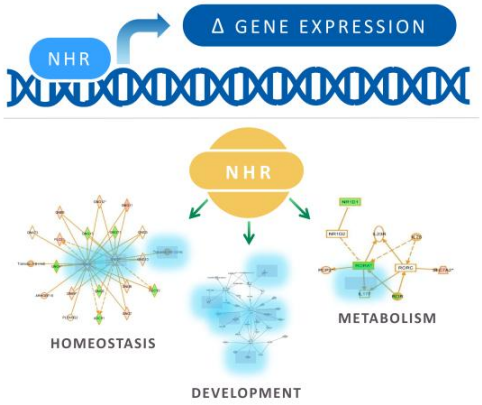
RORA alone regulates expression of several hundred homeostasis genes



Nejati Moharrami et al, PLOS ONE 2018

Why Target Nuclear Hormone Receptor Genes?

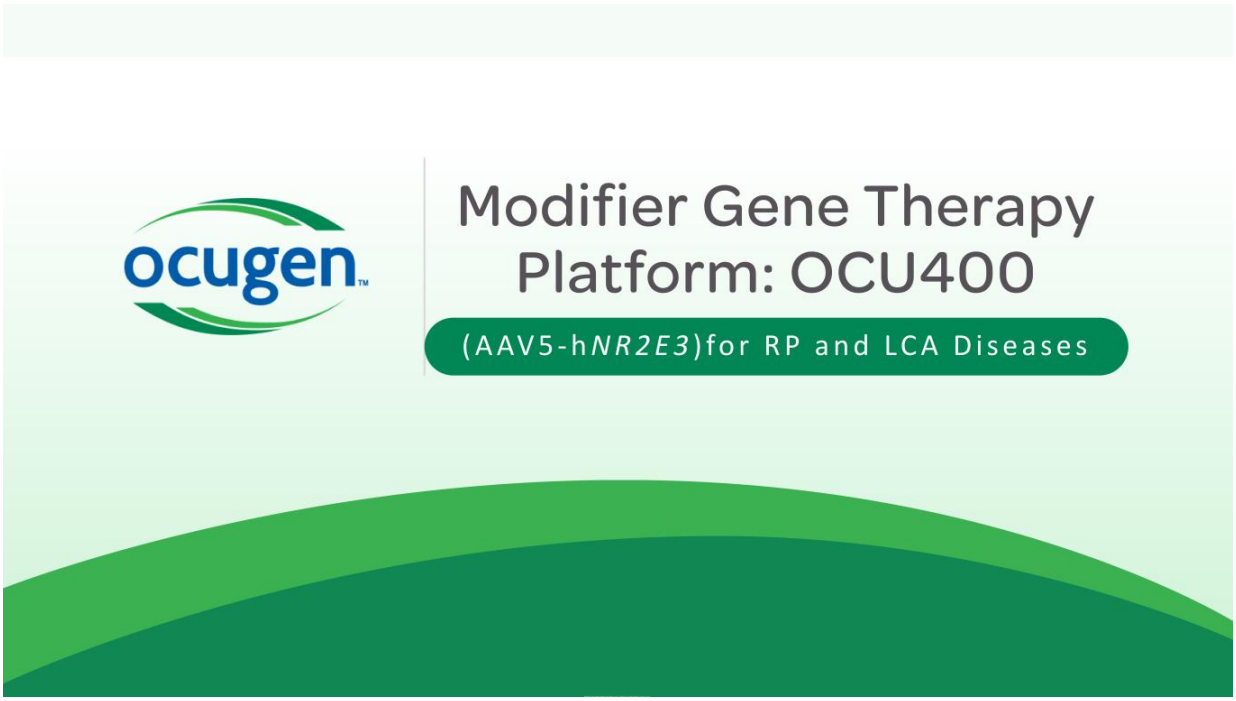
- **Nuclear hormone receptors (NHRs)** are intracellular receptors that **regulate gene expression**
  - NHRs act as **"Master Genes"** inside the cell
- NHRs can regulate diverse physiological functions
  - Homeostasis
  - Cellular and tissue development
  - Cellular and tissue metabolism
- The human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



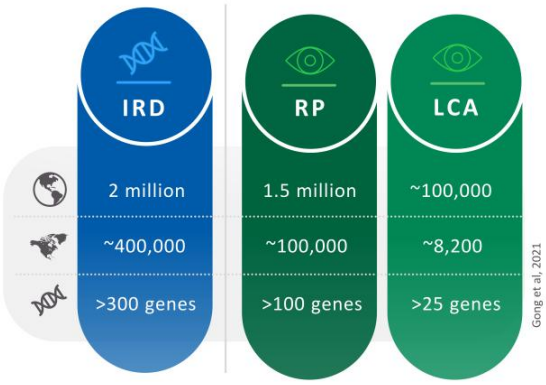
Pipeline Overview: Modifier Gene Therapy Technology

	ASSET/PROGRAM	INDICATION	STATUS
Modifier Gene Therapy Platform	OCU400 **	***Inherited retinal degeneration***	
		NR2E3 Mutation	Phase 1/2
		RHO Mutation	Phase 1/2
		CEP290 Mutation	Phase1/2 to be initiated
	OCU410	**Dry Age-related Macular Degeneration (Dry AMD)***	IND Enabling
	OCU410-ST	**Stargardt Disease**	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


ocugen
Modifier Gene Therapy Platform: OCU400
(AAV5-hNR2E3)for RP and LCA Diseases

Inherited Retinal Diseases: Prevalence and Associated Genes



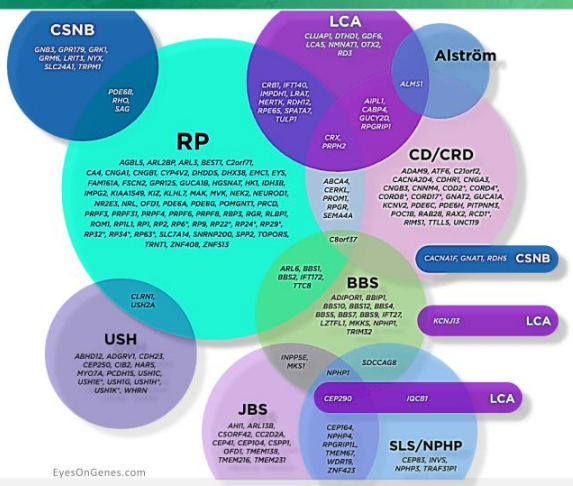
IRDs: Diverse disease class with large phenotypic and genetic heterogeneity

- 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**

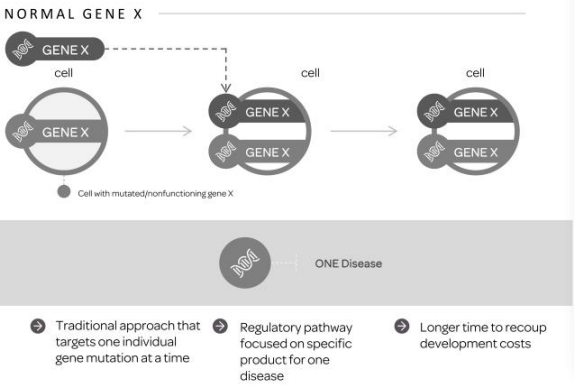
Gene augmentation or editing can only treat a small fraction of the IRD population, but **OCU400 has the potential to treat a large group of patients with IRDs**



EyesOnGenes.com

Current Limitations of Conventional Gene Therapy

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

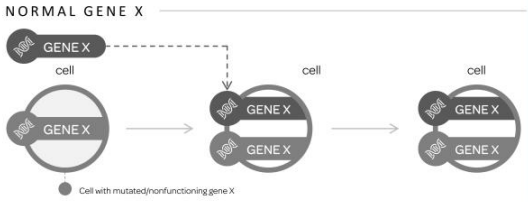


- Traditional approach that targets one individual gene mutation at a time
- Regulatory pathway focused on specific product for one disease
- Longer time to recoup development costs

- 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

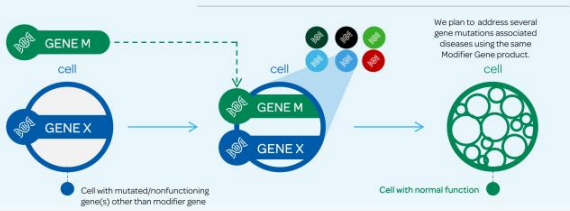
Modifier Gene Therapy: An Innovative Potential Treatment for IRDs

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



- 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

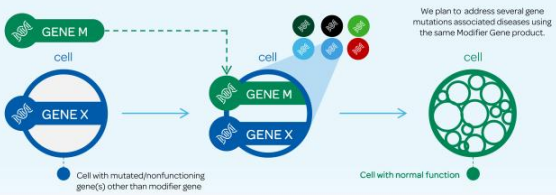
Modifier Gene Therapy: Designed to introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina.



- 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.



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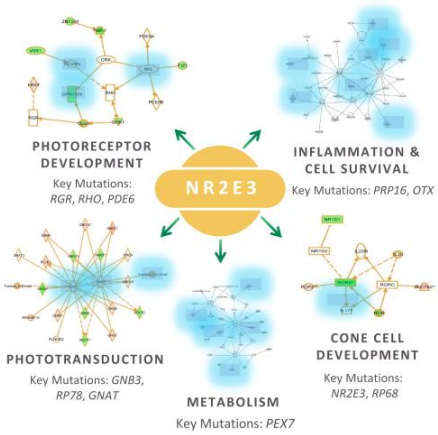
- Potentially smoother regulatory pathway due to ability to target multiple gene mutations with one product
- Ability to recoup development costs over multiple therapeutic indications

> **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

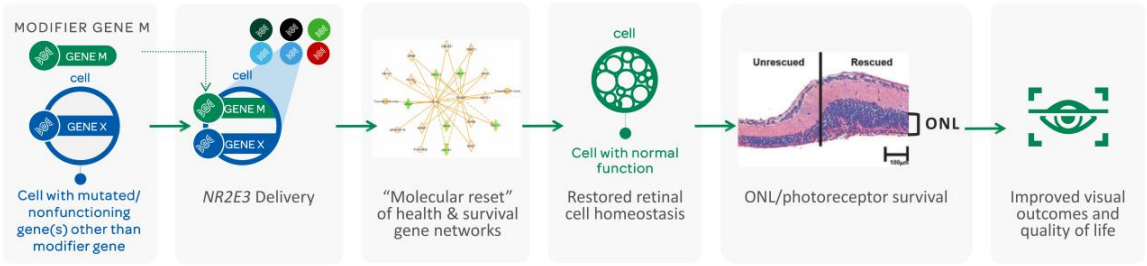
OCU400 Targets the Retina-specific NHR Gene *NR2E3* to Potentially Treat IRDs

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

(PDE6β-associated RP)

2&3

***Rho*$^{-/-}$** and ***Rho*^{P23H}**

(both rhodopsin-associated RPs)

4

rd16

(Leber Congenital Amaurosis)

5

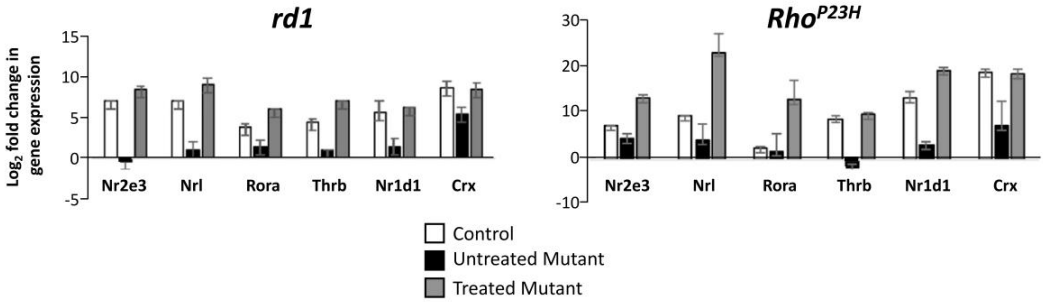
rd7

(Enhanced S-cone Syndrome)

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

***NR2E3* overexpression results in a "molecular reset"**

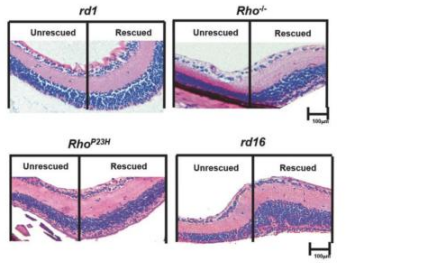
> Restoration of pro-survival and pro-maintenance genes
> Recruitment of transcription factors



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

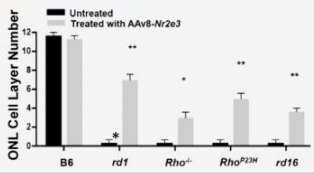
OCU400 Pre-clinical Data: Rescue of Retinal Cell Counts in Early and Advanced Stage Disease

OUTER NUCLEAR LAYER (ONL) STAINING



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

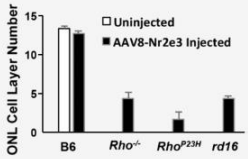
EARLY STAGE RESCUE



Injection: P0

ONL Cell Count: 3-4 months

ADVANCED STAGE RESCUE



Injection: P21

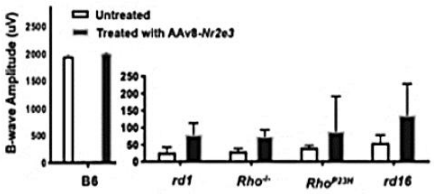
ONL Cell Count: 2-3 months

rd1 evaluated one month post-injection
ONL, outer nuclear layer; **P**, postnatal day
Li S. *Gene Ther*. 2021;28(5):223-241.

OCU400 Pre-clinical Data: Improved ERG Signals

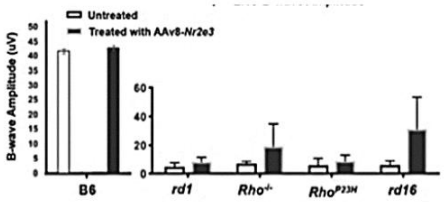
SCOTOPIC: ROD-FOCUSED

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

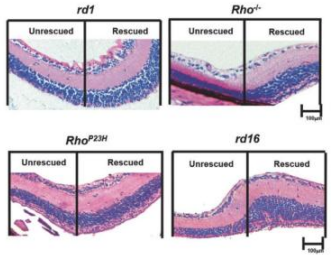
ocugen

ERG response: P0 single subretinal injection, evaluation 3-4 months post injection
Li S. *Gene Ther*. 2021;28(5):223-241.

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
    - Increased expression of pro-cell health and maintenance transcription factors
    - Improved ONL morphology **in early and advanced disease**
    - Rescued retina function (ERG response)

OUTER NUCLEAR LAYER (ONL) STAINING



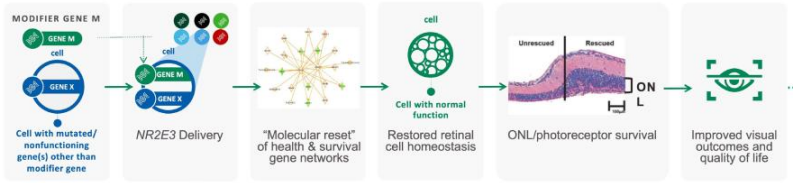
***NR2E3* overexpression can benefit RP disease state across multiple genotypes**

ERG, electroretinogram; **IRD,** inherited retinal degeneration; **NHR,** nuclear hormone receptor; **ONL,** outer nuclear layer; RP, retinitis pigmentosa

Li S. *Gene Ther*. 2021;28(5):223-241.

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**

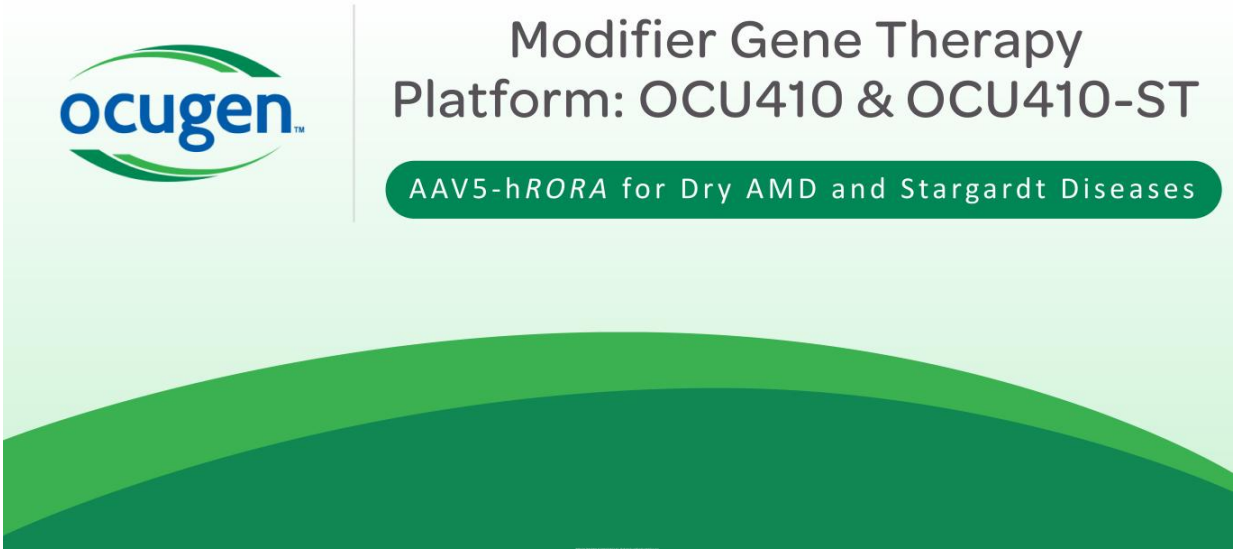
Patient anatomical and potentially **functional benefit in both early or advanced disease stage**

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


ocugen
Modifier Gene Therapy
Platform: OCU410 & OCU410-ST
AAV5-h*RORA* for Dry AMD and Stargardt Diseases

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

AMD

196 million

11 million

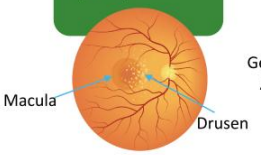
USD 10.52 billion

Global AMD potential treatment market – 2022
www.grandviewresearch.com

AMD

Leading cause of irreversible sight loss in the elderly population

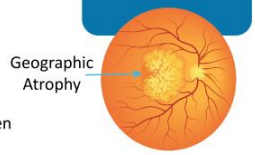
- First manifests in macula with appearance of pigment changes and subretinal deposits (drusen)



Dry AMD

90% of AMD cases

- Non-neovascular
- Leads to geographic atrophy of RPE, choriocapillaries, and photoreceptors
- Risk factor for Wet AMD



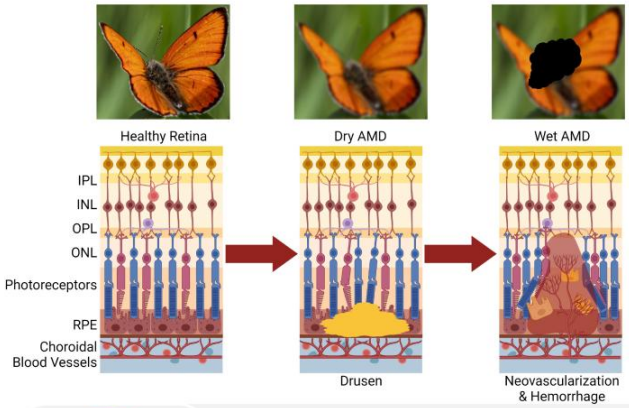
STGD

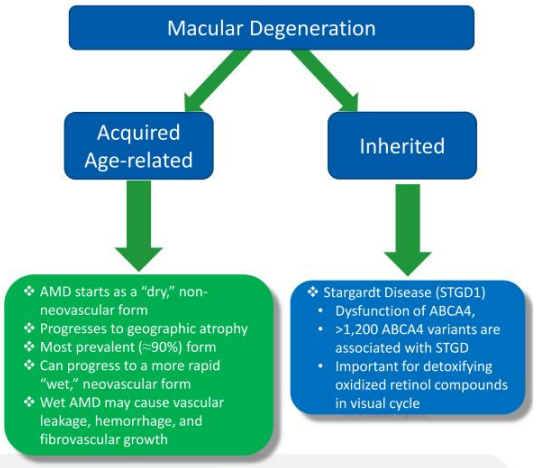
~800,000

~35,000

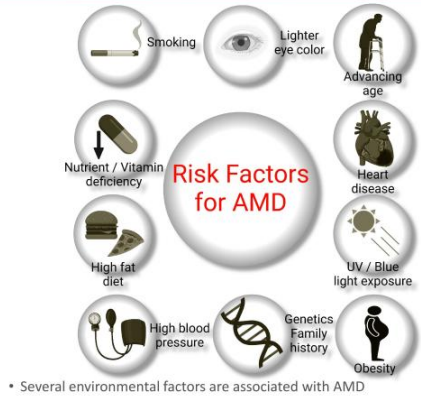
>1200 gene variants

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

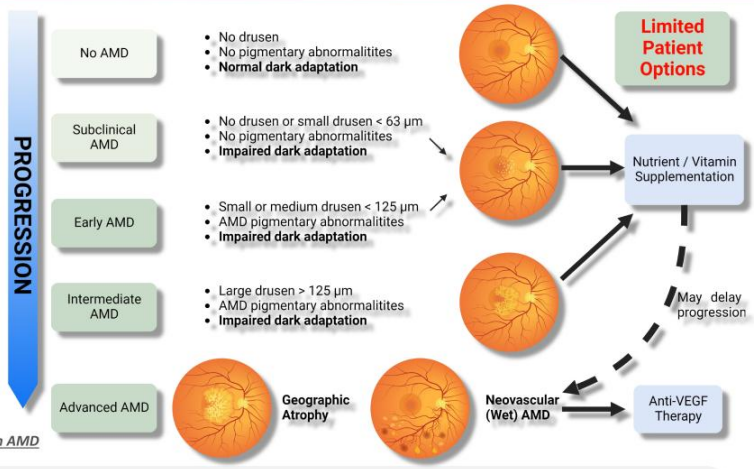




AMD Pathogenesis and *Limited* Treatment Approaches



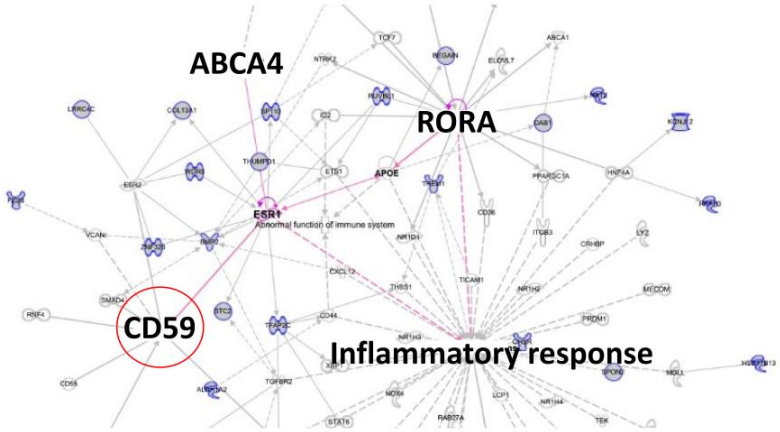
- Several environmental factors are associated with AMD
- Certain polymorphisms in several genes are associated with AMD
- ***A strong role of inflammation, complement, and oxidative pathways in AMD***



RORA regulated gene networks are relevant in AMD and Stargardt disease

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

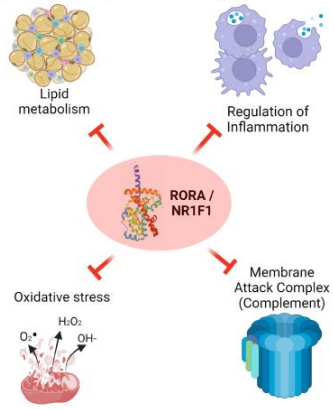
- RORA gene network
- Inflammatory response pathway
- Complement machinery

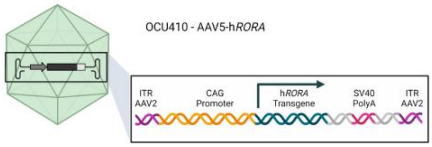


OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD

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

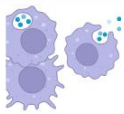
The Retinoic Acid Related (RAR) Orphan Receptor Alpha (**RORA**) regulates several gene networks





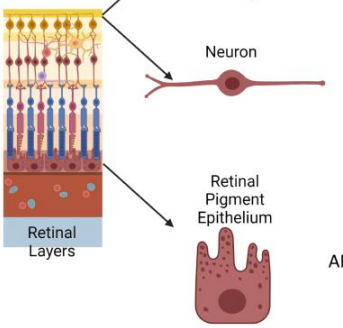
OCU410 is an adeno-associated virus-based vector containing Human *RORA* (isoform 1)

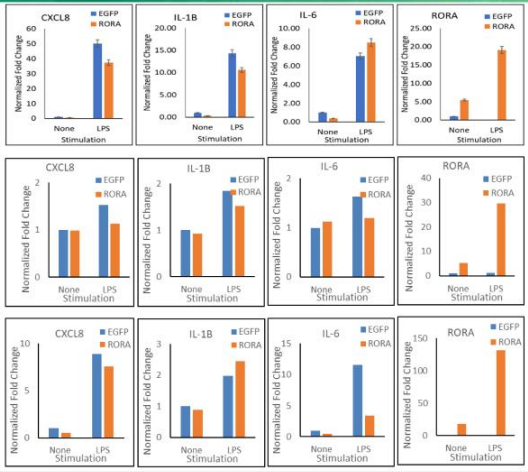
OCU410: Anti-Inflammatory Response



Regulation of Inflammation

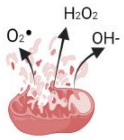
OCU410 suppresses inflammatory response in multiple cell lines



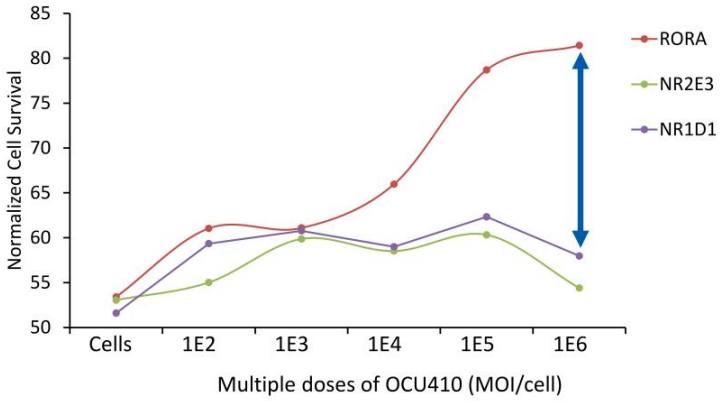


OCU410 Protects Against Oxidative Stress

Oxidative stress

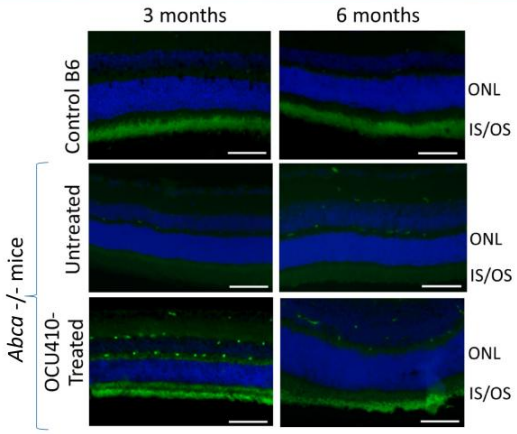


OCU410 Rescues $NaIO_3$ mediated oxidative death in ARPE19 cells



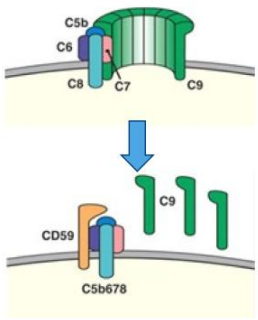
OCU410 Restores CD59 Expression in ABCA4 -/- Mice

- 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)



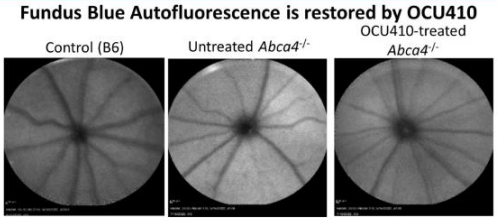
Immunohistochemistry of retina showing CD59 and DAPI

CD59 prevents the formation of the complement membrane attack complex

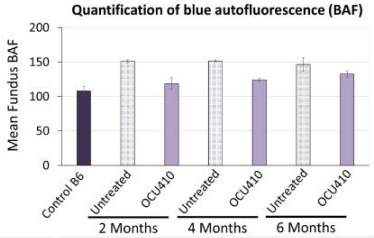


OCU410: Restoring Retinal Function in *ABCA4 -/-* Mice

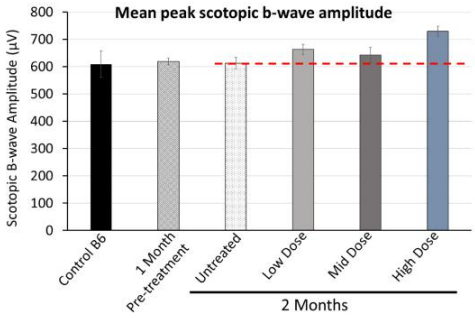
Fundus Blue Autofluorescence is restored by OCU410



Quantification of blue autofluorescence (BAF)



Mean peak scotopic b-wave amplitude



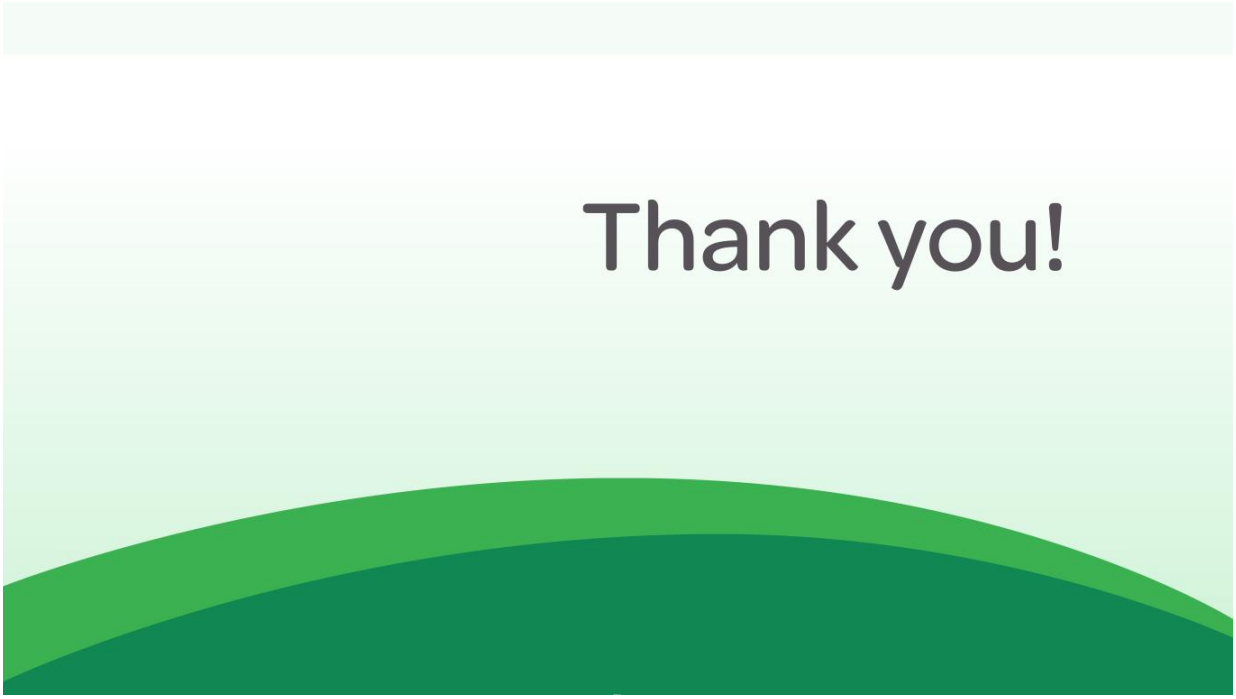
OCU410: Summary

- 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!

COVAXIN a safe and effective whole virus vaccine against SARS-CoV-2

Ocugen Inc. Malvern, PA, United States

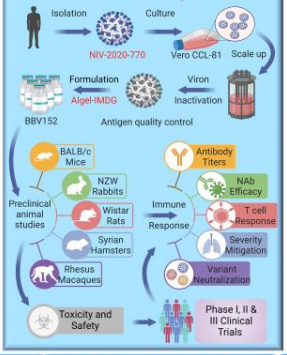
COVID-19 Vaccine Challenges

- Emergence of multiple mutations in Variants of Concern decreases efficacy of existing vaccines
- Immunological: Global SARS-CoV-2 pervasiveness due to viral reservoirs in unvaccinated
- Logistics: Ultra-cold chain storage, lack of community coordination & inaccurate vaccine demand forecast
- Safety: More adverse events after multiple mRNA boosters and insufficient long-term mRNA vaccine data
- Equitable Distribution: Vaccine hesitancy, manufacturing/distribution capacity & vaccine nationalism
- Heterologous Prime-Boost: No safety & efficacy data & clinical trial disparities make comparison difficult
- Neglected Groups: Patients with cancer, kidney disorders, HIV, pregnancy, transplants & children

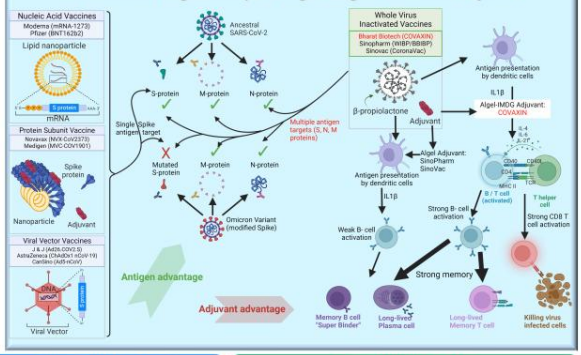
COVAXIN: Rising to the Challenge

- Whole virus inactivated vaccine: Strain NIV-2020-770
- Strong Th1 immune response due to TLR7/8 agonist adjuvant IMDG
- 98.4% Seroconversion, 77.8% protection from symptomatic COVID-19 & 93.4% protection from severe symptoms
- Booster dose provides robust neutralizing antibody titers against Omicron and Delta variants
- The vaccine is stable for 2 years at 2 - 8 °C and 6 months at room temperature
- Strong safety and immunogenicity in adult and pediatric age groups
- EUL in 28 countries and over 350 million doses administered

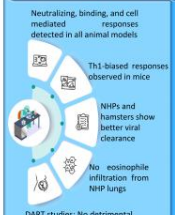
COVAXIN development



The COVAXIN Edge: Multiple antigen targets and IMDG adjuvant

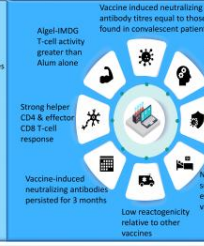


Pre-clinical Studies



DART studies: No detrimental effects in NZW Rabbits

Phase I / II



Phase III & Pediatric Trial

Safety compared to placebo

Solicited adverse events (9.5% vs. 8.2%)
Serious Adverse events (0.3% vs. 0.47%)
similar between both groups

Efficacy

Overall efficacy of 78%
Severe = 93%
Asymptomatic = 63.6%
All 95%CI were above the 50% success criteria

Efficacy against Variants

Kappa: 90.1%
Delta: 65.2%

Immunogenicity

Immunogenicity responses across 3 consecutive GMP lots was equivalent.

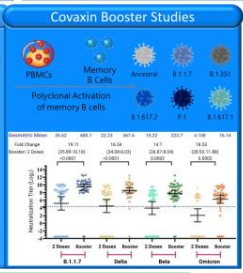
Neutralizing Antibodies

Alpha, Beta, Delta & Omicron

Pediatric study

Children (2-18 y) generated 1.7X higher Nab responses compared to adults

Covaxin Booster Studies



COVAXIN HIGHLIGHTS

- Nonclinical data supports vaccine effectiveness & safety
- Phase 1 & 2 data for safety & persistent immunogenic responses
- Meets all safety data expectations (2 months after the second dose for 25,800 participants)
- Efficacy against cases of severe COVID-19
- Final efficacy with a point estimate over 50%
- Neutralization data published against Alpha, Beta, Delta & Omicron
- Vaccine benefits outweigh its risks based on Phase 3 clinical trial
- Consistent manufacturing (lot to lot consistency)
- Robust AEFI system in-place
- Post marketing safety underway
- Trials in HIV infected, pregnant individuals are being planned

COVAXIN Emergency Use Listing

Ocugen Clinical Studies

A Phase 2/3, Immuno-bridging, and Broadening Study of a Whole, Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Adults 18 to 65 years of age with no prior history of COVID-19

Study Type	Placebo-Controlled
Estimated Enrollment	400 participants
Allocation	Randomized
Intervention Model	Parallel assignment
Intervention Model Description	1:1 randomization ratio

NCT: 05258669 →

Immuno-bridging and Broadening Study (OCU002) — *Interim Analysis*

Safety Study (OCU003)

Age Group	Participants	Gender	Participants
18 - <65	380 (90%)	Female	230 (54.5%)
>=65	42 (10%)	Male	192 (45.5%)

Interim Blinded Safety Summary:

Serious Adverse Event (SAE)	0
AE of Special Interest (AESI)	0
Medically Attended AE (MAAE)	None related to IP
Potential Immune Mediated Medical Conditions (PIMMC)	0

No incidence of myocarditis, pericarditis, thrombocytopenia & Guillain Barre syndrome

COVAXIN® PUBLICATIONS

Complete List

PRECLINICAL TRIALS

- CelPress — Hamster Efficacy Study
- nature communications — Non-Human Primate Efficacy Study
- CelPress — Preclinical Safety and Immunogenicity

CLINICAL TRIALS

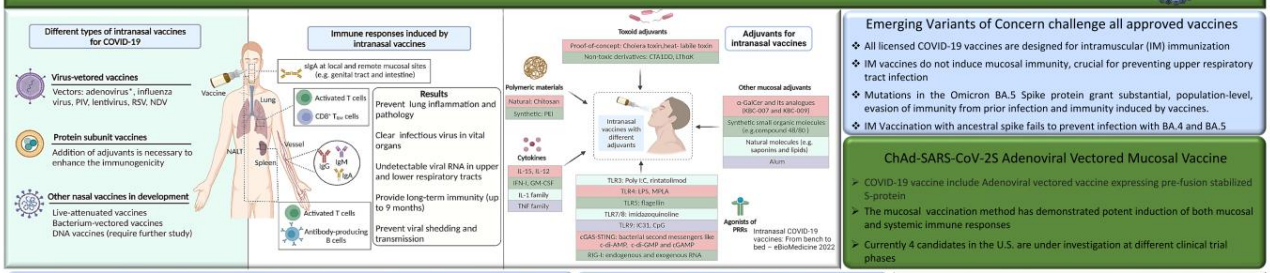
- medRxiv — Booster Dose
- medRxiv — Pediatric Study 2-18 years
- THE LANCET Infectious Diseases — Phase 3
- THE LANCET Infectious Diseases — Phase 2
- Phase 1

NEUTRALIZATION OF VARIANTS

- Alpha (B.1.1.7)
- Clinical Infectious Diseases — Kappa (B.1.617.1)
- Gamma (P.2 & 1.128)
- Beta and Delta (B.1.351 & B.1.617.2 respectively)

Recombinant Adenoviral-Vectored Mucosal Vaccine against SARS-CoV-2

Ocugen Inc. Malvern, PA, United States



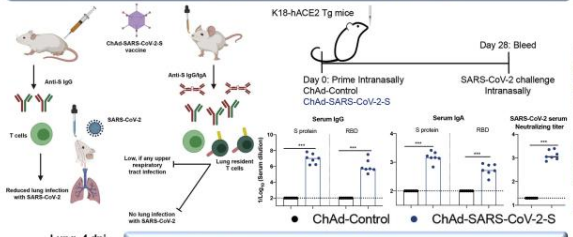
Emerging Variants of Concern challenge all approved vaccines

- All licensed COVID-19 vaccines are designed for intramuscular (IM) immunization
- IM vaccines do not induce mucosal immunity, crucial for preventing upper respiratory tract infection
- Mutations in the Omicron BA.5 Spike protein grant substantial, population-level, evasion of immunity from prior infection and immunity induced by vaccines.
- IM Vaccination with ancestral spike fails to prevent infection with BA.4 and BA.5

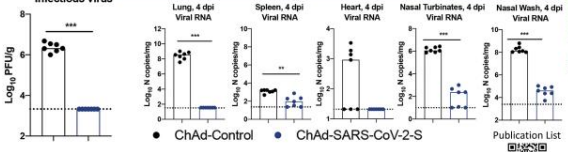
ChAd-SARS-CoV-2S Adenoviral Vectored Mucosal Vaccine

- COVID-19 vaccine include Adenoviral vectored vaccine expressing pre-fusion stabilized S-protein
- The mucosal vaccination method has demonstrated potent induction of both mucosal and systemic immune responses
- Currently 4 candidates in the U.S. are under investigation at different clinical trial phases

A single intranasal dose of ChAd-SARS-CoV-2-S promotes systemic and mucosal immunity and induces high levels of IgG and IgA (mucosal) neutralizing antibodies

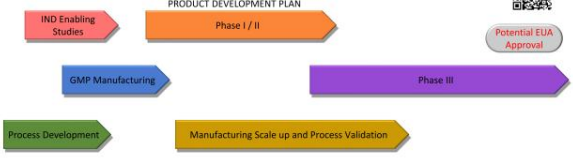


Intranasal ChAd-SARS-CoV-2-S significantly lowers local and systemic viral load

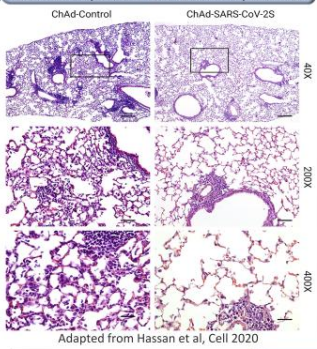


Publication List

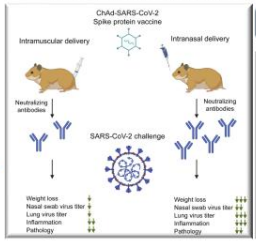
MUCOSAL VACCINE
PRODUCT DEVELOPMENT PLAN

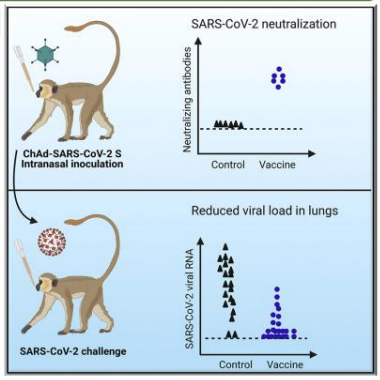


Mice immunized with single-dose intranasal ChAd-SARS-CoV-2-S protected from SARS-CoV-2 pneumonia

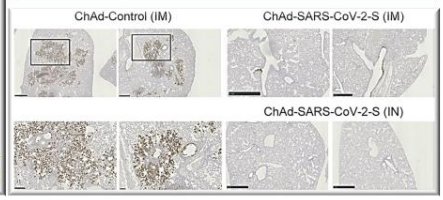


Adapted from Hassan et al, Cell 2020





Hamsters immunized with single-dose intranasal ChAd-SARS-CoV-2-S protected from SARS-CoV-2 infection

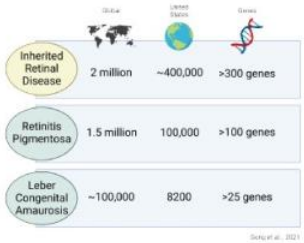


OCU400: A Modifier Gene Therapy for Retinitis Pigmentosa and Congenital Amaurosis

Ocugen, Inc., Malvern, PA, United States

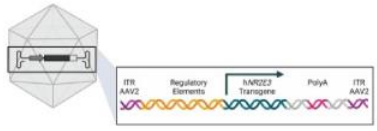
INTRODUCTION

- Retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA) are inherited retinal diseases (IRDs) with a worldwide prevalence of 1 in 4,000 and 3 in 100,000, respectively
- They are characterized by abnormalities in rod and cone photoreceptors
- LCA develops early in childhood, whereas RP develops over time
- In RP, progressive retinal degeneration often starts in the mid-periphery and advances toward the macula and fovea
- RP and LCA are caused by many different gene mutations



OCU400 (AAV5-h*NR2E3*)

- OCU400 is a nuclear hormone receptor-based modifier gene therapy product consisting of an AAV5 capsid containing the human *NR2E3* transgene
- Granted **Orphan Drug Designations (ODDs)** for the treatment of ***NR2E3, RHO, CEP290,*** and ***PDE6B*** mutations-associated IRDs from US FDA
- Received **Orphan medicinal product designations** for the treatment of **RP** and **LCA** from EMA

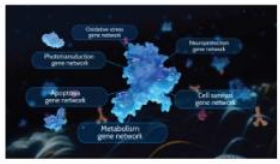


OCU400 consists of two inverted terminal repeats (ITRs) flanking regulatory elements, h*NR2E3* transgene, and poly A sequence.

NUCLEAR HORMONE RECEPTORS AS MODIFIER GENE THERAPY

- **Nuclear hormone receptors (NHRs)** are intracellular receptors that **regulate gene expression**
- NHRs can regulate diverse physiological functions, acting as **"Master Genes"** inside the cell, such as:
  - 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
- Modifier gene therapies leverage these functions to provide an alternative to traditional gene replacement therapy

Retinal Gene Networks Regulated by *NR2E3*, a retina-specific NHR



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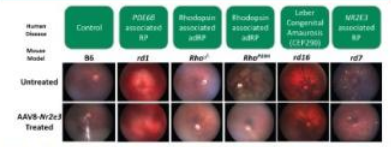
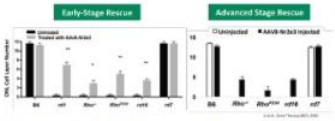
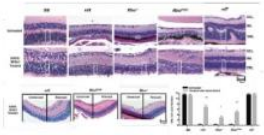


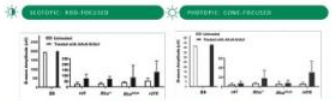
OCU400 rescues retinal degeneration in multiple RP and LCA mouse models



OCU400 rescues survival of photoreceptors in outer nuclear layer in early and advanced stages of disease



OCU400 rescues retina's structural integrity

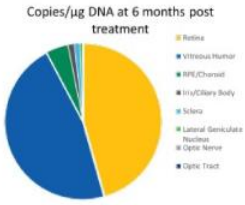


OCU400 enhances the retina's ERG response, which could mean improved vision for patients with IRDs

SAFETY AND BIODISTRIBUTION

OCU400:

- Specifically distributed in retina and RPE/choroid with sustained protein expression in retina
- No systemic distribution
- Good safety profile for overall clinical and ocular health
- Modest ADA response against AAV5 in mid and high dose groups
- No cell-based immune response against the drug product



AAV5-h*NR2E3* vector distribution in ocular tissues following subretinal administration

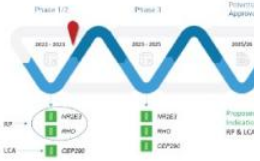
NR2E3 transgene protein expression in retina

CLINICAL STU

- Positive DSMB recommendations after reviewing safety
- No Serious Adverse Events (SAEs) related to the investig

PRODUCT DEVELOPMENT AND P

- Process optimization and scale-up to s manufacturing is established and clinic been generated
- Efficacy established in multiple RP and
- Safety profile established in minipig
- IND was successful
- Phase 1/2 clinical trial - patient enrollm
- Phase 3 manufacturing, process chara process validation for BLA are in progr



Gong et al., Clin Ophthalmol 15, 2021
Li et al., Gene Therapy, 28(5), 2020

OCU410: A Modifier Gene Therapy for Dry Age-Related Macu Degeneration and Stargardt Disease

Ocugen, Inc., Malvern, PA, United States

INTRODUCTION

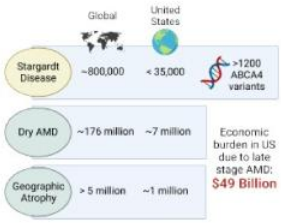
Dry age-related macular degeneration (AMD) and Stargardt are ocular diseases that lead to blindness

Dry AMD

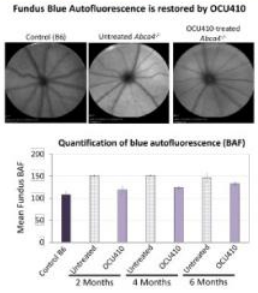
- Over 170 million people are affected worldwide
- ~90% of dry AMD cases convert to a more severe form of AMD
- Advanced dry AMD is also known as geographic atrophy (GA); ~1 million people affected in the US
- In GA, retinal pigment epithelium (RPE) and photoreceptor cells are significantly degenerated

Stargardt Disease (STGD)

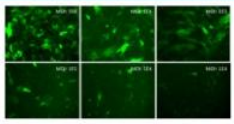
- Rare disease that affects 1 in 8,000-10,000 people worldwide
- ~30,000-35,000 people affected with STGD in the US
- Clinically characterized by slow loss of central vision in both eyes from early childhood to youth
- Common symptoms include gray, black, or hazy spots in the visual center, sensitivity to light, longer dark adjustment duration, and color blindness
- Underlying common cause is mutations in the ABCA4 gene, which follows an autosomal recessive pattern of inheritance



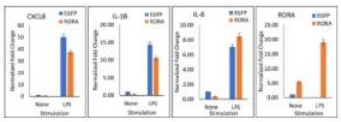
OCU410 REDUCES DRUSEN IN STARGARDT (ABCA4$^{-/-}$) MODEL



OCU410 SUPPRESSES INFLAMMATORY CYTOKINE RESPONSE

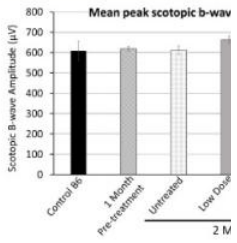


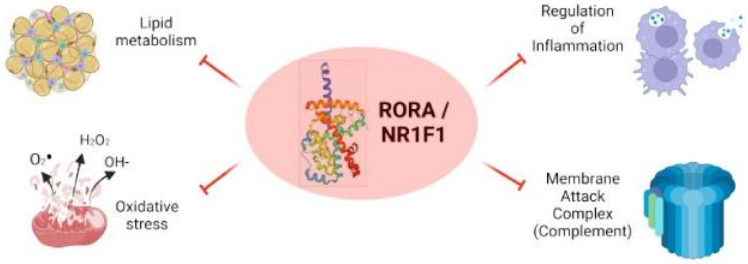
Dose-dependent increase in transduction of microglial cells



Cytokine expression following stimulation with lipopolysaccharide (LPS)

OCU410 IMPROVES RETIN



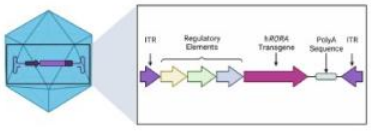


SAFETY AND DISTR

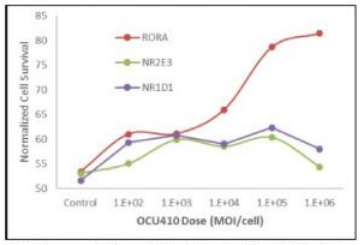
- Dose response pharmacc in dry AMD and Stargardt models in progress
- Subretinal route of admin observed to be optimal fc delivery in dry AMD and S
- OCU410 was well-tolerat dose range studymm
- A 2-month non-GLP toxic provided a range of safe OCU410
- A 6-month GLP toxicity st progress to determine sa biodistribution of drug pr

OCU410 (AAV5-*hRORA*)

OCU410 (AAV5-h*RORA*) is a nuclear hormone receptor based gene therapy intended to treat these diseases using a modifier gene therapy approach

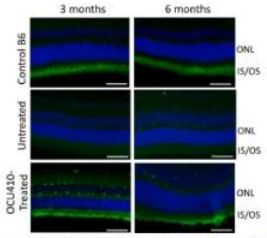


OCU410 RESCUES OXIDATIVE DEATH IN VITRO



OCU410 rescues $NaIO_3$-mediated oxidative death in ARPE19 cells in a dose-dependent manner

OCU410 INCREASES CD59, A COMPLEMENT PATHWAY INHIBITOR



Immunohistochemistry of retina showing CD59 and DAPI

DEVELOPMENT TI

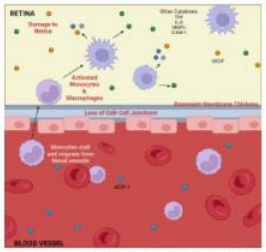
REFERENCE

Foundation for Fighting Blindness, 2
Schultz et al., Clinical Therapeutics 4

OCU200: A Novel Therapeutic Offering Benefits Beyond Anti-VEGF for Dia Retinopathy, Diabetic Macular Edema, & Wet Age-Related Macular Degene

Ocugen, Inc., Malvern, PA, United States

DIABETIC MACULAR EDEMA AND WET AMD



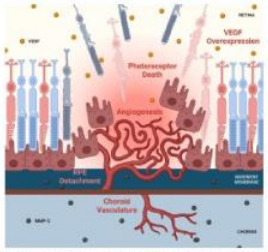
Pathophysiology of Diabetic Macular Edema (DME)

Diabetic Retionpathy (DR) and Diabetic Macular Edema (DME)

- DR progresses to DME
- Leads to retinal abnormalities and vision loss
- Blood-Retina Barrier breakdown leads to intraretinal hemorrhages, exudates, and macular edema

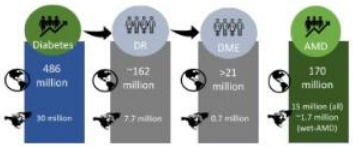
Wet Age-Related Macular Degeneration (Wet AMD)

- Leading cause of blindness worldwide
- Angiogenesis and edema damage overlying structures, including retinal pigmented epithelium (RPE) layer
- VEGF known to play a key role

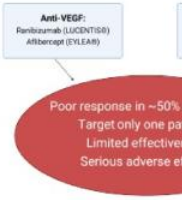


Pathophysiology of Wet Age-Related Macular Degeneration (WetAMD)

PREVALENCE AND CHALLENGES

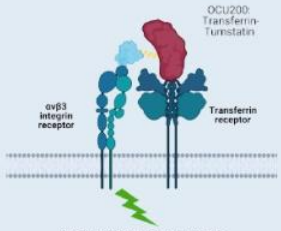


Prevalence of Diabetes, Diabetic Retinopathy, Diabetic Macular Edema, and Wet Age-Related Macular Degeneration



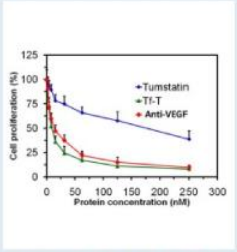
Challenges with Currently App

DESCRIPTION OF OCU200, MECHANISM OF ACTION, AND PRE-CLINICAL RESULTS

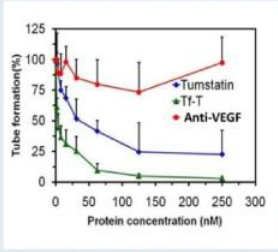


Transferrin enhances delivery of fused proteins across cellular barriers (including retinal barriers). It allows targeting of anti-angiogenic peptide to proliferating endothelial cells (a hallmark of neovascularization).

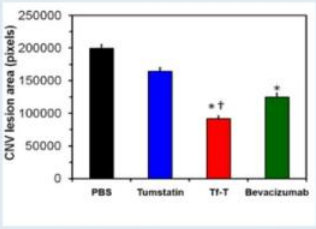
Tumstatin is an endogenous angiogenesis inhibitor derived from the C-terminus non-collagenous domain (NC1) of collagen IV. It inhibits neovascularization by binding to αVβ3 integrins.



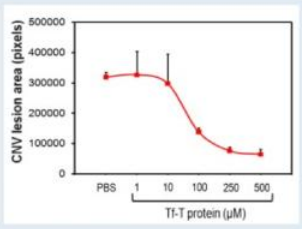
OCU200 (Tf-T) inhibits VEGF-induced HUVC cell proliferation



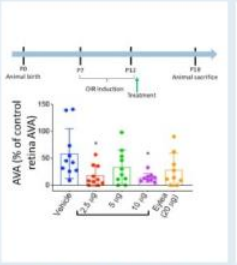
OCU200 (Tf-T) inhibits tube formation in endothelial cells



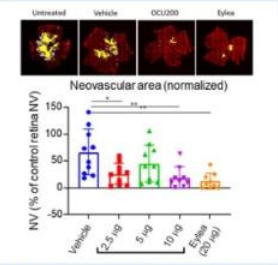
OCU200 (Tf-T) showed superior efficacy as compared to bevacizumab and tumstatin alone. * indicates p<0.05 when compared to PBS and/or tumstatin treatment. † indicates p<0.05 when compared to bevacizumab. Data is expressed as mean ± S.D.



OCU200 (Tf-T) reduces CNV lesion area in dose dependent manner, at concentrations ranging from 1 to 500 nM. Data is expressed as mean ± S.D.



OCU200 reduces avascular areas (AVAs) comparable to aflibercept but at a lower dose



OCU200 inhibits neovascularization (NV) comparable to aflibercept but at a lower dose

CONCLUSION

- Proof-of-concept study demonstrated potential of OCU200 in the treatment and Wet-AMD
- Distinct mechanism of action through integrin pathway will provide benefit t responders) to currently approved the

PATH TO THE CLINIC (PHA

- Currently conducting IND-enabling pre and toxicology studies
- GMP manufacturing complete
- IND submission by Q1 2023
- Initiation of Phase I ascending dose e

NeoCart®: The Cutting-Edge Treatment for Knee Articular Cartilage Defects.

List of Authors
Ocugen Inc. Malvern, PA, United States

Knee Cartilage Damage: A Complex Problem

Cartilage:
- A complex shock absorber
- Withstands significant pressure
- Allows for rolling & sliding

Immediate Problems:
- Damage from acute injury or repetitive trauma
- Debilitating pain and loss of function

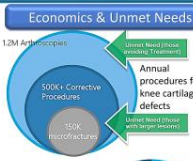
Long term Problems:
- Limited regeneration - lack of vascularity
- Strong correlation with Osteoarthritis

Cartilage Injury
Focal Chondral Defect

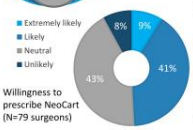
Current treatment options are sub-optimal with variable outcomes due to variable cellular response

Patients and physicians seeking alternatives that offer a more rapid and durable recovery

Economics & Unmet Needs of Knee Repair: The NeoCart Advantage

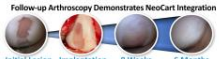


Annual procedures for knee cartilage defects



Willingness to prescribe NeoCart (N=79 surgeons)

Follow-up Arthroscopy Demonstrates NeoCart Integration



- Powerful, proprietary platform that provides restorative cell therapies (RCTs) for active living
- NeoCart®, is a proprietary RCT that rebuilds patients' own knee cartilage, reducing pain at the source and potentially prevents progression to osteoarthritis (OA)
- Large market opportunity to treat knee cartilage damage approximately 1.2M defects identified each year
- Clinically meaningful Phase 3 top-line results reported in Q3:18
- Planned expansion of NeoCart platform into additional markets and indications

The NeoCart® Breakthrough

- NeoCart: bio-engineering breakthroughs enhance the autologous cartilage repair
- Accelerated healing and reduced pain using patient's own cells in a 3D scaffold
- Patients receive functional cartilage at the time of treatment

Attributes of an Optimal Treatment for Knee Cartilage Damage

- Reduces pain
- Improves function
- Promotes repair of damaged cartilage
- Short rehabilitation / rapid return to daily activities
- Durable response
- No specialized surgical techniques and less operating room time
- Non-opioid approach

Potential Benefits of NeoCart®

- Patient Satisfaction: pain relief, better QoL, improved productivity
- Physician Satisfaction: robust clinical data – 1-year superiority endpoint
- Payer Cost Effectiveness

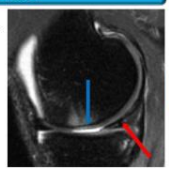
Phase I

Study parameters:
- Treatment group – 8 patients
- Cartilage injury – 1-2 cm

Evaluations:
- Through 60 months post-op
- International Knee Documentation Committee (IKDC) questionnaire
- Visual analog scale
- Range of motion
- Cartilage-sensitive MRI

Results:
- Lowered pain and improved functions after NeoCart
- Six patients had substantial defect fill at 24 months
- Improved IKDC score in 7 out of 8 patients

Safety:
- No adverse events reported
- No patient developed arthrofibrosis or implant hypertrophy



• Sagittal MRI and arthroscopic image of the NeoCart implant (blue arrow) at 12 weeks with meniscal tear (red arrow).
• The NeoCart (blue arrow) is flush & integrated to repaired region (border shown by black line) (Crawford et al., AJSM 2009)

Coronal MRI shows good fill of the cartilage defect 10 days to 6 months after NeoCart Implantation (Crawford et al., AJSM 2009)

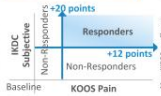
NeoCart Publications

Clinical Trials:

Phase II

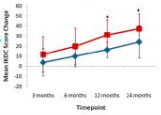
Study parameters:
- 30 patients at 6 U.S. centers
- 2:1 randomization (NeoCart v. Microfracture)
- Lesion size – 1-3 cm

Superiority Endpoint: % of NeoCart "Responders" vs Mfx "Responders"

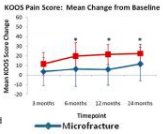


Evaluations: 60 months post-op
- IKDC questionnaire
- Knee Injury and Osteoarthritis Outcome Score (KOOS) for pain, symptoms, activities of daily living (ADL), quality of life (QOL), sports scales, Visual analog scale and Short Form-36 (SF-36) questionnaire

IKDC Score: Mean Change from Baseline



KOOS Pain Score: Mean Change from Baseline



Results:
- More patients responded to NeoCart than microfracture
  - at 6 months (43% Vs 25%)
  - at 12 months (76% Vs 22%)
- Improvement with NeoCart was significantly greater
  - at 6, 12 and 24 months for IKDC, SF-36 & KOOS-ADL / pain
  - at 6 months for KOOS-symp
  - at 12 & 24 months for KOOS sports & VAS

Safety:
- No serious adverse events reported
- None of the AE were related to either treatments

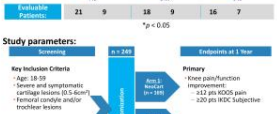
Change in Patient-Reported Outcomes From Baseline to Final Follow-up

Parameter	Baseline	Final Follow-up	Change From Baseline	P -Value	n
IKDC subjective	47.9 ± 17.4	75.5 ± 22.1	27.6 ± 19.1	<0.0001	29
VAS mean	34.6 ± 22.5	14.3 ± 18.4	−20.3 ± 24.6	<0.0001	29
VAS highest	60.1 ± 20.6	23.5 ± 27.0	−36.6 ± 29.7	<0.0001	21
KOOS-Pain	64.8 ± 12.1	86.1 ± 17.3	21.4 ± 10.7	<0.0001	21
KOOS-ADL	75.3 ± 14.8	91.6 ± 13.8	16.1 ± 11.0	<0.0001	21
KOOS-QoL	28.6 ± 15.5	69.4 ± 28.0	40.8 ± 27.5	<0.0001	21
KOOS-Symptoms	65.8 ± 13.8	86.6 ± 13.4	20.8 ± 15.4	<0.0001	21
KOOS-Sports	41.4 ± 24.3	72.4 ± 28.8	31.0 ± 26.4	<0.0001	21
SF-36 physical	40.5 ± 7.2	51.4 ± 8.1	11.0 ± 7.1	<0.0001	21
SF-36 mental	55.1 ± 9.2	54.8 ± 6.7	−0.3 ± 9.5	0.8858	21
Active ROM	131.5 ± 7.9	140.7 ± 6.3	9.2 ± 9.6	<0.0001	29

Data are reported as mean ± SD unless otherwise indicated. Anderson et al AJSM 2017

Phase III

Phase 3 requires only ~15-20% difference between NeoCart and microfracture



Study parameters:

Primary endpoint narrowly missed	NeoCart (N=170)	Microfracture (N = 79)	P-value*
Primary Efficacy Endpoint (ITT)	n/N (%)	n/N (%)	
Clinically significant improvements of ≥12 points in KOOS pain score and ≥20 points in IKDC subjective score at 1 year	121/170 (71.2)	49/79 (62.0)	0.0744

* Pearson's Asymptotic P-Value (1-sided)

HIGHLIGHTS FROM HISTOGENICS PHASE III STUDY

- A prospective randomized trial comparing NeoCart to the microfracture in the treatment of cartilage defects in the knee
- NeoCart narrowly missed the primary endpoint of a statistically significant improvement in pain and function
- Both NeoCart & microfracture were well tolerated with strong safety profiles
- Improvements in KOS subscales (ps 0.050) and IKDC subscales (P=0.0126) favoring NeoCart® at 1 year
- Secondary outcomes met their target goals

Ocugen Phase III

A PROPOSED RANDOMIZED COMPARISON OF NEOCART® TO A COMPARATOR ARM FOR THE KNEE ARTICULAR CARTILAGE REPAIR

COMBATING CONFOUNDERS: PROPOSED ALTERATIONS IN STUDY DESIGN

- *A dynamic randomization design should result in equipoise in the baseline confounders.*
- *Ad hoc analyses demonstrated improvement in pain and function for the NeoCart group vs. microfracture for the following factors:*
  - *Larger lesion sizes*
  - *Younger patients*
  - *Larger BMI (Body Mass Index)*
- *These confounding factors will be controlled for using dynamic randomization in addition to:*
  - *Baseline KOOS (Knee Injury and Osteoarthritis Outcome Score) pain*
  - *Baseline KOOS ADL (Activities of Daily Living)*
  - *Maximum ICRS (International Cartilage Repair Society) Score on MRI*

PRIMARY OUTCOMES

EFFICACY: To demonstrate that NeoCart®, improves pain and function in the repair of knee cartilage defects and is superior to the comparator.

SAFETY: To evaluate NeoCart® safety up to 5 years post-implantation

CO-PRIMARY EFFICACY ENDPOINT

Mean change from baseline to 2 years for the Patients' Knee Injury and Osteoarthritis Outcome Score (KOOS) Pain and Function Activities of Daily Living (ADL) subscale scores.

SECONDARY SAFETY OBJECTIVE

To evaluate NeoCart® safety in the repair of cartilage defects of the femoral condyles and/or trochlea.

NeoCart Highlights: Improved Outcomes Versus Established Suboptimal Alternatives

	NeoCart	Micro-fracture	ACI & other Products
• Accelerated recovery and improved clinical efficacy	✓	×	×
• Shorter recovery times	✓	×	×
• Excellent safety profile	✓	×	×
• Long term performance	✓	×	×
• Fewer complications and re-operations	✓	×	×
• Tissue quality and competence at implantation	✓	×	×
• Biomechanical competence after 1 year	✓	×	×
• Earlier weight-bearing and return to activity	✓	×	×