UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **July 15, 2021**

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)

263 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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 8.01 Other Events

On July 15, 2021, Ocugen, Inc. (the "Company") issued a press release announcing that it had initiated a rolling submission to Health Canada for COVAXIN™, the Company's candidate vaccine against COVID-19, which it is co-developing with Bharat Biotech International Limited for the U.S. and Canadian markets. A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Additionally, attached as Exhibit 99.2 and incorporated herein by reference is a presentation that the Company will post on its website on July 15, 2021 and may use from time to time in presentations or discussions with investors, analysts, and other parties.

Item 9.01 Financial Statements and Exhibits

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press release of Ocugen, Inc. dated July 15, 2021
99.2	Ocugen, Inc. Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 15, 2021

OCUGEN, INC.

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

Exhibit 99.1

Ocugen, Inc. Announces Initiation of Rolling Submission to Health Canada for COVAXIN™

MALVERN, Pa, July 15, 2021 (GLOBE NEWSWIRE) — Ocugen, Inc. (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19, today announced that it had initiated a rolling submission to Health Canada for COVAXIN™, the company's candidate vaccine against COVID-19, which it is co-developing with Bharat Biotech International Ltd. for the U.S. and Canadian markets. This follows the release by Bharat Biotech of Phase 3 clinical trial results, which demonstrated efficacy and safety in nearly 25,800 adults.

The rolling submission process was recommended and accepted under the Minister of Health's *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* and transitioned to a New Drug Submission for COVID-19, which permits companies to submit safety and efficacy data and information as they become available. Often referred to as a rolling review, this allows Health Canada to start its review right away, as information continues to come in, to accelerate the overall review process. Ocugen initiated the rolling submission through its affiliate, Vaccigen, Ltd**.** Health Canada will make a decision upon review of the evidence submitted that supports its safety, efficacy and quality.

"We thank Health Canada for their upcoming review of COVAXIN™ and look forward to working with them so that we can offer the possibility of another safe and effective option to be used in their fight against COVID-19 and its Delta variant," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer and Co-Founder of Ocugen.

About COVAXIN™
COVAXIN™, a COVID-19 vaccine by Bharat Biotech, was developed in collaboration with the Indian Council of Medical Research (ICMR) — National Institute of Virology (NIV). COVAXIN™ is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform with an excellent safety track record, having been used to develop more than 300 million doses of its inactivated vaccines. It is a two-dose vaccine given four weeks apart.

In addition to generating strong immune response against multiple antigens, COVAXIN™ is designed to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. Phase 3 clinical trial data demonstrates efficacy and safety against COVID-19 and its Delta variant. COVAXIN™ is packaged in multi-dose vials that can be stored at 2-8°C.

Based on the more than 30 million doses supplied in India and other countries, COVAXIN™ has an excellent safety record. COVAXIN™ is currently being administered under emergency use authorizations in 13 countries, and applications for emergency use authorization are pending in more than 60 additional countries. COVAXIN™ is considered an investigational drug in Canada and the United States and has not been approved or authorized for use in those countries.

About Ocugen, Inc.
Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with one drug — "one to many" and our novel biologic product candidate aims to offer better therapy to patients with underserved diseases such as wet age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. We are co-developing Bharat Biotech's COVAXIN™ vaccine candidate for COVID-19 in the U.S. and Canadian markets. For more information, please visit www.ocugen.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties. 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 forward-looking statements include information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, including the risk that such dates are not met due to impacts from the ongoing COVID-19 pandemic, as well as risks associated with preliminary and interim data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that the results of in-vitro studies will not be duplicated in human clinical trials; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from Bharat Biotech's clinical trials will be published in scientific journal publications and, if so, when and with what modifications; whether we will be able to provide the U.S. Food and Drug Administration (FDA) with sufficient additional information regarding the design of and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India in order for those trials to support a biologics license application (BLA); the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a BLA; any additional chemistry, manufacturing and controls information that we may be required to submit the timing of our BLA filing; whether and when a BLA for COVAXIN™ will be submitted to the FDA; whether and when a BLA may be approved by the FDA or an application for authorization under interim order for emergency use may be approved by Health Canada, which approvals will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; whether developments with respect to COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada or other jurisdictions; manufacturing capabilities or capacity, including whether sufficient doses of COVAXIN™ can be manufactured within our projected time periods; market demand for COVAXIN™ in the United States or Canada; decisions by the FDA or Health Canada impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States or Canada, including development of products or therapies by other companies. 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. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events or otherwise, after the date of this press release.

Ocugen Contact:
Ken Inchausti
Head, Investor Relations & Communications
+1 484 237 3398
ken.inchausti@ocugen.com

Please submit investor-related inquiries to: IR@ocugen.com

ocugen

Our Mission is to

Develop **Gene Therapies** to Cure Blindness Diseases

and

Develop a **Vaccine** to Save Lives from COVID-19

NASDAQ: OCGN

Corporate Deck: July 2021

Forward Looking Statement

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our business strategy, future results of operations and financial position, prospective products, product approvals, research and development costs, timing and likelihood of success, estimated market size or growth, and plans and objectives of management for future operations, are forward-looking statements When used in this presentation, the words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements involve known and unknown risks, uncertainties and other factors, including those risks set forth in the Company's filings with the Securities and Exchang Commission, which are available at www.sec.gov, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements are based on our management's beliefs and assumptions and on information available to management as of the date of this presentation. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statement even if new information becomes available in the future.

This presentation includes estimates by us of statistical data relating to market size and growth and other estimated data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. This presentation also includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicat that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securitie shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Ocugen Overview

VACCINE	• **COVAXIN™:** Whole-virion inactivated COVID-19 vaccine candidate (with adjuvant). Licensed rights from Bharat Biotech for the and Canadian markets (currently received EUA in India). Standard vaccine storage condition (2-8°C) • Demonstrated 77.8% overall efficacy, 93.4% in severe COVID-19 disease (including hospitalization) and 65.2% efficacy against Delta variant in Phase 3 trial by Bharat Biotech • Phase 3 clinical trial enrolled 25,800 participants between 18-98 years of age, including 2,760 over the age of 60 and 7,058 wit at least one pre-existing condition. Phase 1/2 enrolled 755 participants • Potential coverage against multiple protein antigens of the virus and potentially applicable to broader population, including 12 17-year-olds (as seen in Phase 2 study) • Effectively neutralizes additional Kappa, Zeta, and Alpha variants of SARS-Cov-2 reducing the possibility of mutant virus escape • Rolling submission initiated with Health Canada (July 2021)
MODIFIER GENE THERAPY PLATFORM	• Potential for one product to treat many diseases & multi-factor approach (POC study results published in Nature) • **OCU400 (AAV-hNR2E3):** Orphan medicinal product designation for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA) covering diseases caused by mutations in over 175 genes. Initiation of Phase 1/2a this year • **OCU410 (AAV-hRORA):** Potential to treat dry age-related macular degeneration (Dry AMD) through multi-factor treatment approach – initiation of Phase 1/2 in 2022 • Strategic manufacturing partnership with CanSinoBio (~$13B market cap) – sets clear path for critical manufacturing
NOVEL BIOLOGIC	• **OCU200:** Targeting major retinal diseases: Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Wet Age-Related Macular Degeneration (Wet AMD) (estimated global market size over $10B) – initiation of Phase 1/2 in 2022 • Novel MoA: Potential to initially treat non-responders to anti-VEGF/ therapies (~50% of patients)

Leadership Team

Shankar Musunuri, PhD, MBA
Chairman, CEO and Co-Founder

Sanjay Subramanian, MBA
CFO and Head of Corporate Development

Bruce D. Forrest, MB, BS, MD, MBA
Acting CMO

J.P. Gabriel
SVP, Manufacturing & Supply Chain

Vijay Tammara, PhD
SVP, Regulatory & Quality

Michael Shine, MBA
SVP, Commercial

Arun Upadhyay, PhD
VP, Head of Research & Development

Jessica Crespo, CPA
Corporate Controller and Treasurer

Zara Gaudioso, SHRM-CP
Head of Human Resources

Scientific Advisory Boards

Retina Scientific Advisory Board

David Boyer, MD

Carl D. Regillo, MD, FACS

Mark Pennesi, MD, PhD

Geeta Lalwani, MD

Vaccine Scientific Advisory Board

Satish Chandran, PhD

David Fajgenbaum, MD, MBA, MSc, FCPP

Bruce D. Forrest, MB, BS, MD, MBA

Catherine Pachuk, PhD

Harvey Rubin, MD, PhD

Susan Weiss, PhD

Pipeline and Regulatory overview

	Asset/Program	Indication	Phase	Notes
VACCINE	**COVAXIN™** Whole-Virion Inactivated Vaccine	COVID-19	Phase 3*	Rolling submission initiated with Health Canada (July 2021); Discussions with FDA ongoing
MODIFIER GENE THERAPY PLATFORM	**OCU400** AAV-hNR2E3	**NR2E3 Mutation –** Associated Retinal Degeneration**	IND-Enabling	Orphan designation US & EU†
		RHO Mutation – Associated Retinal Degeneration**	IND-Enabling	
		CEP290 Mutation – Associated Retinal Degeneration**	IND-Enabling	
		PDE6B Mutation – Associated Retinal Degeneration**	IND-Enabling	
	OCU410 AAV-hRORA	**Dry Age-Related Macular Degeneration (Dry AMD)**	Preclinical	
NOVEL BIOLOGIC	**OCU200** Transferrin – Tumstatin	**Diabetic Macular Edema**	Preclinical	
		Diabetic Retinopathy	Preclinical	
		Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical	

*Bharat Biotech-sponsored clinical trial

** No approved therapies exist

https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment

https://www.aao.org/eye-health/diseases/amd-treatment

† EU orphan medicinal product designation for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA)

COVAXIN™

Whole-Virion Inactivated COVID-19 Vaccine Licensed from Bharat Biotech (BBIL) for the US and Canadian Markets

COVAXIN™ - Product Profile

Whole virion inactivated SARS-CoV-2 (NIV-2020-770)
Antigen concentration & Adjuvant: 6µg + Algel–IMDG(TLR7/8)

PROPOSED INDICATION	Active Immunization to Prevent COVID-19 caused by SARS-CoV-2
TARGET POPULATION	12 years of age and older
DOSE LEVEL and REGIMEN	0.5mL per dose suspension 2 Doses: Day 0 & Day 28
PRESENTATION	10 doses per vial
STORAGE	2°- 8°C (Expected shelf-life ~2 Yrs.) Room temp (25ºC): 3 Months

Why COVAXIN™

Designed to fill a significant unmet need in our North American arsenal of vaccines against COVID-19

B

Broad Spectrum Immune Response

Both humoral & cellular responses generated against multiple viral proteins
Induces a Th1 response (cell-mediated immunity)

E

Efficacy → 77.8% Efficacy Demonstrated in Phase 3 Trial (93.4% against severe)

Effective in neutralizing multiple variants, including rapidly-spreading Delta variant (65.2% efficacy)
Potentially serve as a universal booster to minimize/eliminate viral escape and control the Pandemic

S

Safe in 12+ (Demonstrated in Phase 2 clinical trial)

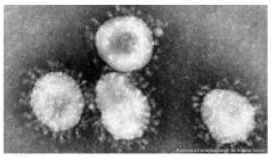
Proven technology platform and supply chain currently used for several licensed vaccines (Influenza, Polio, Rabies, JEV etc.).
Historically demonstrated acceptable safety, tolerability and efficacy consistent with adults

T

Transportation and Storage Ease

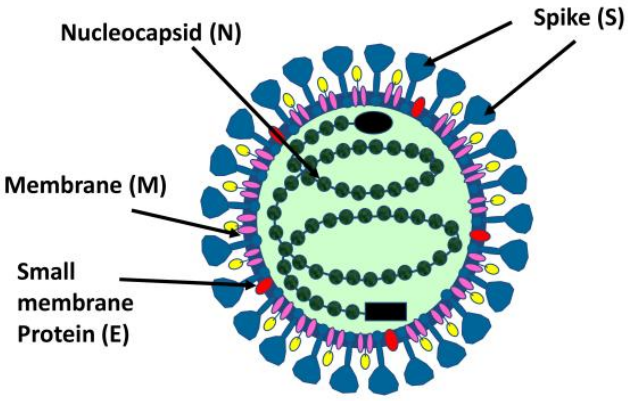
Stable for 3 months at room temperature
Can be stored in standard conditions (2°- 8°C) for several years. Can be stockpiled.

COVAXIN™ Presents Multiple Protein Targets to the Immune System Resulting in Broad Spectrum Response

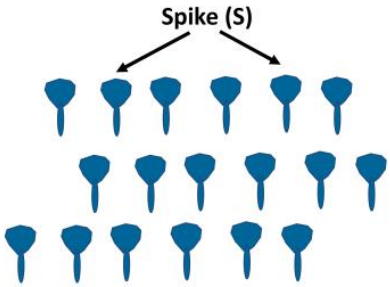


COVAXIN™, an adjuvanted inactivated virus vaccine candidate, elicited strong IgG responses against spike (S1) protein, receptor-binding domain (RBD), and the nucleocapsid (N) protein of SARS-CoV-2 along with strong cellular responses

COVAXIN™



mRNA and Adenovirus-Based Vaccin



COVAXIN™ Developed and Manufactured by Bharat Biotech

Established Robust Manufacturing Process for COVAXIN

Ocugen licensed COVAXIN™ on the back of Bharat's strong track record of developing & commercializing vaccines globally

Inactivated Vero cell derived vaccines are proven, time-tested and long-lasting. A few include:

ROTAVAC®
ORAL ROTAVIRUS VACCINE 116E, LIVE ATTENUATED

JENVAC®
PURIFIED, INACTIVATED JAPANESE ENCEPHALITIS VACCINE

INDIRAB®
PURIFIED, INACTIVATED RABIES VACCINE

ONGOING VACCINE CANDIDATE USING VERO CELL PLATFORM

- CHIKUNGUNYA
- ZIKA
- sIPV
- BBV152*

*COVAXIN

~25 CLINICAL STUDIES

~300,000 SUBJECTS

15 YEARS EXCELLENT CLINI TRIAL SAFETY

~300 MILLION DOSES SUPPLIED FROM VERO MANUFACTURING PLATFORM | EXCELLENT POST MARKETING SAFETY RECORD

COVAXIN™ is Distinct Amongst Leading COVID-19 Vaccines and Select Vaccine Candidates in the United States and Canada

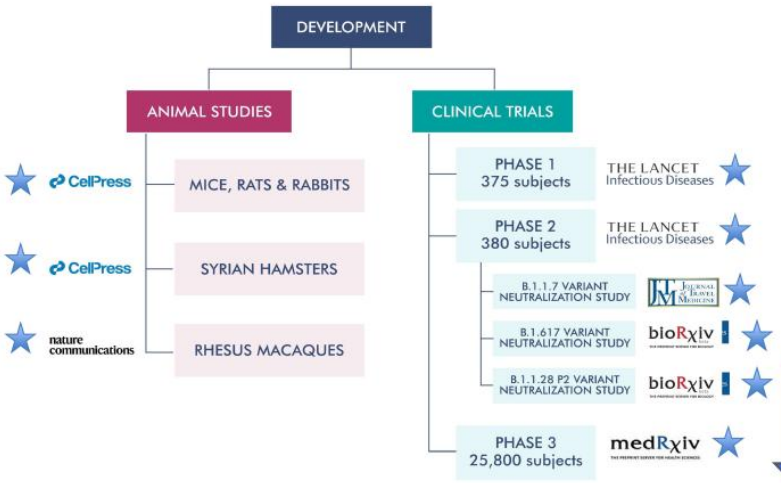
Company	Technology	Antigen	Status in US & Canada
COVAXIN™	Inactivated SARS CoV-2 Virus, Aluminum hydroxide, TLR agonist	Whole virus (Including S & N Proteins)	Rolling submission initiated with Health Canada; BLA submission to be pursued in US
Pfizer/ BioNTech	Lipoplex of SARS CoV-2 S protein mRNA	S protein	EUA in US; Authorized by Interim Order in Canada
Moderna	Lipoplex of SARS CoV-2 S protein mRNA	S protein	EUA in US; Authorized by Interim Order in Canada
AstraZeneca	Non-replicating infectious Adenovirus	S protein	Authorized by Interim Order in Canada
Johnson & Johnson	Non-replicating infectious Adenovirus	S protein	EUA in US; Authorized by Interim Order in Canada

Technology Comparisons: Target Product Profile

Characteristic	mRNA	Adeno- Based	COVAXIN™
Acceptable Safety	✓	✓	✓
Neutralizing antibody response	✓	✓	✓+
Cellular responses against multiple viral antigens	✓	✓	✓+
Efficacy	✓	✓	✓+
Stability at 2-8°C	X	✓	✓
Multiple Viral Antigens	X	X	✓

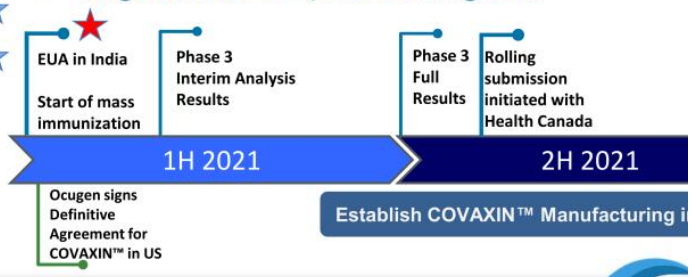
"+" : B and T cell immune responses to multiple proteins, Safety and Efficacy in Phase 3 clinical trial by Bharat Biotech

COVAXIN™ Progress and Planned Milestones for North American Development



Click ★ to access publication

- Phase 3 data analysis completed
- Rolling submission initiated with Health Canada
- BLA submission to be pursued in US; discussions o to determine filing pathway
- Initial US Supply from Partner, BBIL
- Execute Tech Transfer to US Sites
- Target 100M Doses/Year Starting 2021



FINAL Phase 3 Clinical Trial Results Demonstrate Protective Effect of COVAXIN™

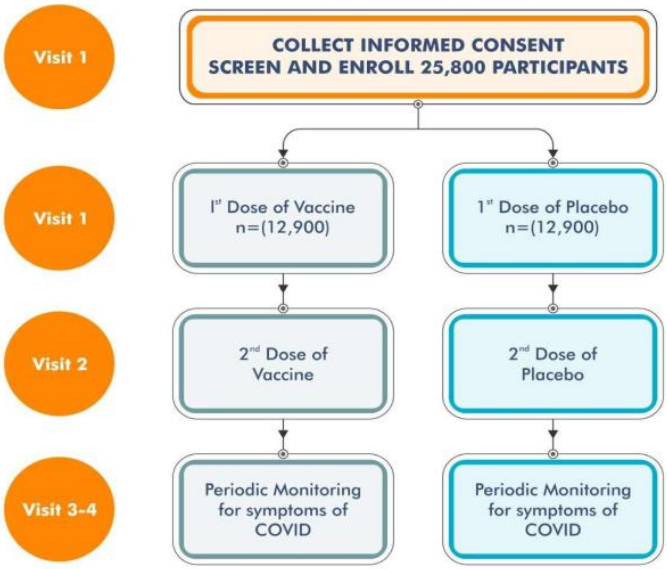
Fast facts of a double-blind, randomized, multicenter, Phase 3 clinical trial

- Subjects recruited between November 2020 and January 2021 across 25 sites
- 1:1 randomization among healthy adults (age 18-98 years)
- n = 25,798
- Primary endpoint: Preventing symptomatic COVID-19 occurring at least 14 days after second dose
- Secondary endpoint: Efficacy in subgroups based on age (18 - <60 years; ≥60 years)
- Evaluated safety, reactogenicity and consistency of immune responses

- ✓ **Overall vaccine efficacy: 77.8%** (95% CI: 65.2 – 86.
- ✓ **Efficacy against severe disease: 93.4%** (95% CI: 57 – 99.8)
- ✓ **Efficacy against asymptomatic disease: 63.6%** (95 CI: 29.0 – 82.4)
- ✓ **Safety outcomes: 12.4%** reported adverse events (AE) in vaccine or placebo arms (p<0.05)
  - Most frequently reported systemic AEs included headache, followed by pyrexia, fatigue and myalgia
  - Serious AEs were reported by <0.5% of clinical trial participants
- ✓ **Demonstrated Efficacy against B.1.617.2 (Delta): 65.2%** (95% CI: 33.1 – 83.0)
  - *First Phase 3 clinical trial to include Delta variant data*

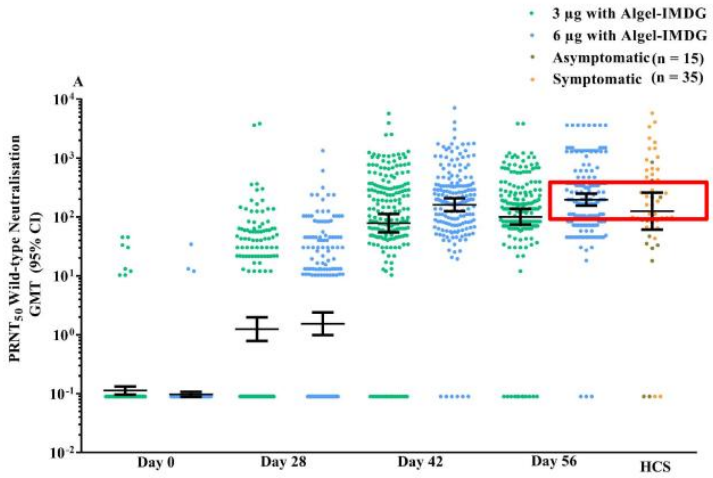
Source: Efficacy, safety, and lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): a, double-blind, randomised, controlled phase 3 trial; Ella, Reddy, Blackwelder, Potdar, et al.; medRxiv 2021.06.30.21259439; accessed July 7, 2021

Phase 3: Study Outline

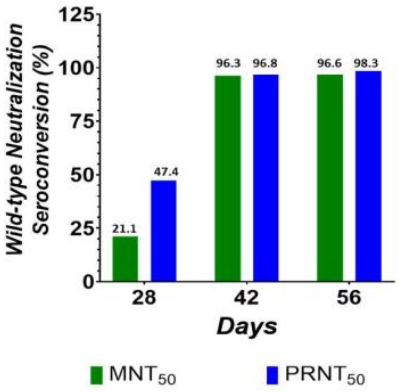


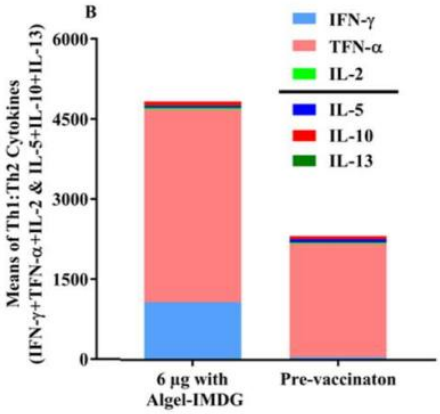
Phase 2: Study Results

- **6µg +Algel-IMDG** demonstrated high neutralizing Abs responses **compared to 3µg + Algel-IMDG grou**
- Mean GMT (95% CI) **higher than human convalescent serum (HCS)**
- 6µg +Algel-IMDG (**Covaxin™**) selected for Phase 3 study



Phase 2: Study Results





Safety

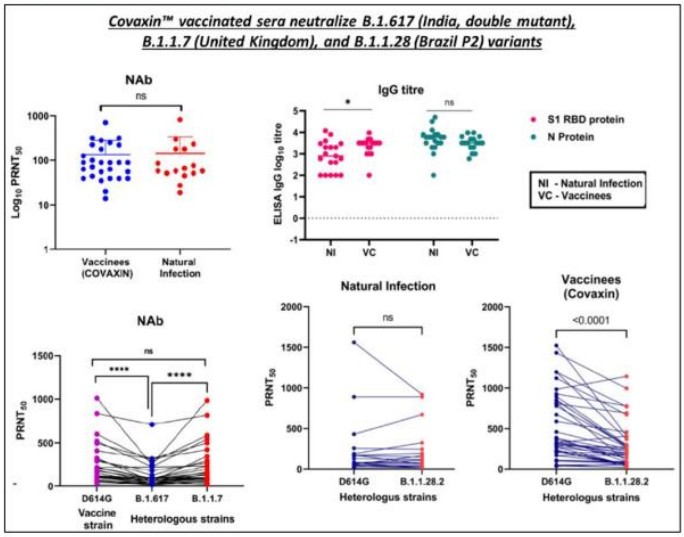
Events	Rate (%)
Local	4.2% (1.8, 8.1)
Systemic	7.4% (4.1, 12.1)
Serious	0%
Combined	**10.3% (7.4, 13.8)**

- **High Seroconversion rates (>96%) in both MNT50 and PRNT50 measured up to day 56**
- **Induction of Th1 cell mediated immunity as measured by IFN-γ, IL-2, TNF-α**

- **No vaccine-related severe or l threatening adverse events reported to date**

Additional Research Demonstrating Effect Against Multiple Variants

- **COVAXIN-vaccinated sera effectively neutralized several SARS-CoV-2 variants in an in-vitro plaque reduction neutralization assay**



- ✓ B.1.617 (India - Kappa)
- ✓ B.1.1.7 (United Kingdom - Alpha)
- ✓ B.1.1.28 (Brazil P2 - Zeta)

- **The study was conducted by Indian Council of Medical Research (ICMR)-National Institute of Virology**
- **These studies suggest that COVAXIN vaccination may be effective against multiple SARS-CoV-2 variants.**

Ocugen's Modifier Gene Therapy Platform

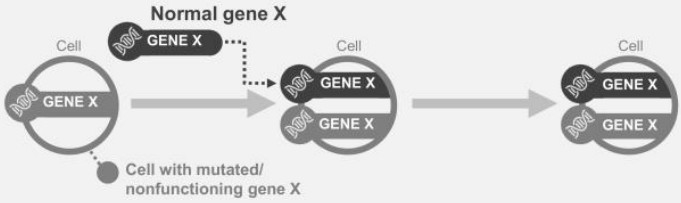
Breakthrough Technology Designed to

Address Multiple Diseases with One Product

Approach Complex Diseases Through Multiple Factors

Traditional Approach vs. Ocugen's Novel Platform

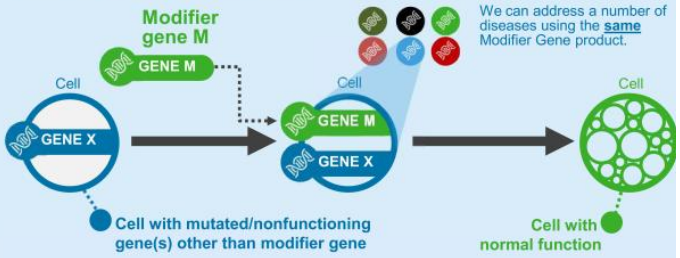
Gene Augmentation: Transfer functional version of a non-functional gene into the target cells.



Traditional Gene Therapy

- 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: Introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina



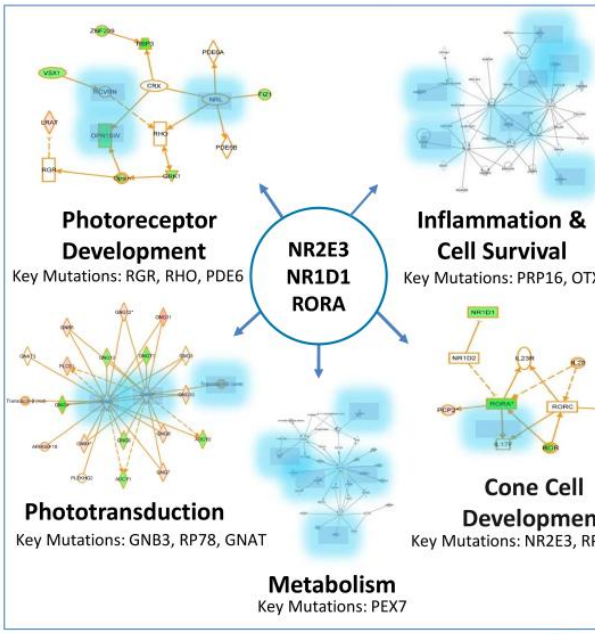
OCU400

Broad Spectrum Therapy for R

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

Why Target Nuclear Hormone Receptor Genes (NHRs)?

- Modulators of retinal development & function
- Act as “master genes” in the retina
- Molecular reset of key transcription factors and associated gene networks – retinal homeostasis
- Gene modifier concept including impact on clinical phenotypes is well known in other disease areas, CF and SMA *

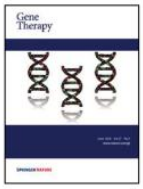


* References: https://pubmed.ncbi.nlm.nih.gov/28556246/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409218/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339951/
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183526

Nature Gene Therapy Publication

Preclinical POC Data for *Nr2e3* Published in *Nature Gene Therapy*

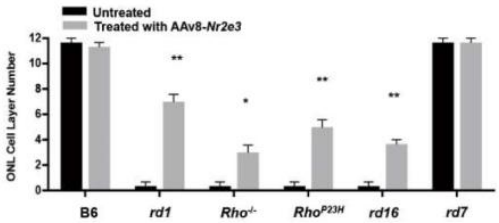
- **Efficacy results shown in 5 unique mouse models of RP**
- **Technology developed at Harvard Medical School, Dr. Neena Haider's Lab**
- **Study demonstrates potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits early and advanced stages of RP**
- **Results show evidence of vision rescue in Early & Advanced Stages of disease**



- Important milestone for development of therapy; demonstrated proof of principle
- Protection elicited in multiple animal models of degeneration caused by different mutations
- Potential to represent first broad-spectrum therapy and to provide rescue even after disease onset

OCU400 – Rescue in Early & Advanced Stage of Disease

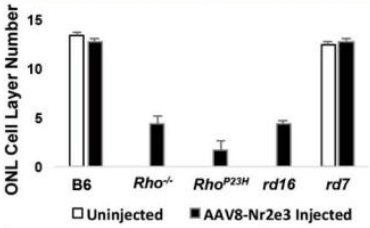
Early Stage Rescue



- P0 single subretinal injection, evaluation 3-4 months post injection
- *rd1* evaluated one-month post injection

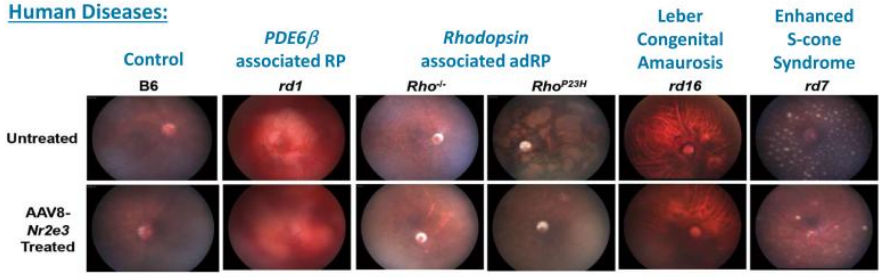
ONL: Outer Nuclear Layer

Advanced Stage Rescue



- P21 subretinal injection, evaluation 2–3 months post injection
- Restored ONL photoreceptors morphology in rd7
- ONL cell layer change in *rd7* model doesn't progress until 4-5 mos. of age

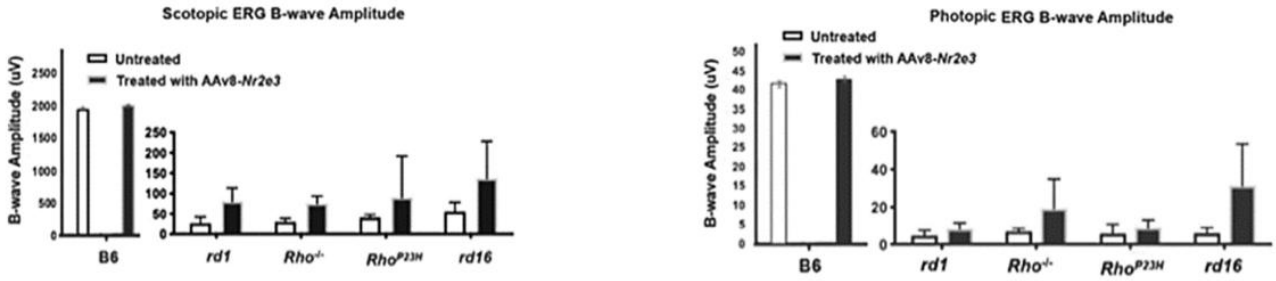
Human Diseases:



➢ **Fundus images and ONL count show how single product recuses vision in multiple mutations**

OCU400 – Demonstrates Improved Vision Signals in Retina

Electroretinogram (ERG) Response Reveals Rescue under Both Scotopic (dim-lit) as well as Photopic (well-lit) Conditions



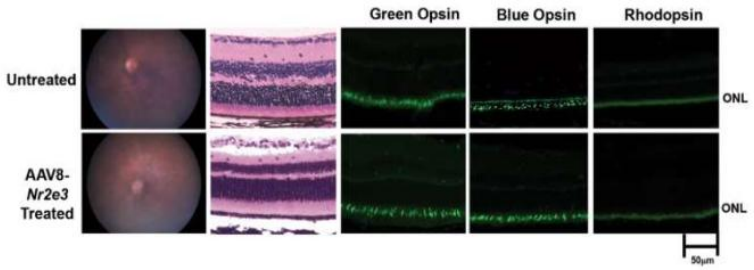
ERG response: P0 single subretinal injection, evaluation 3-4 months post injection

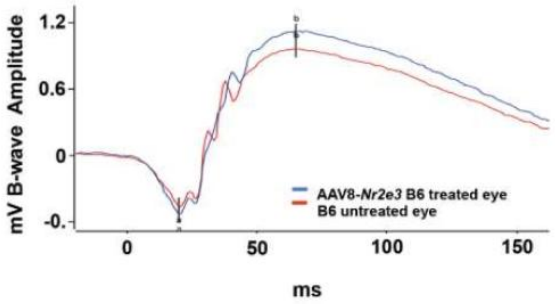
Human vision is enabled by three primary modes:

- **Photopic vision:** Vision under well-lit conditions, which provides for color perception and functions primarily due to cone cells in the eye
- **Mesopic vision:** A combination of photopic vision and scotopic vision in low lighting, which functions due to a combination of roc and cone cells in the eye
- **Scotopic vision:** Monochromatic vision in very low light, which functions primarily due to rod cells in the eye

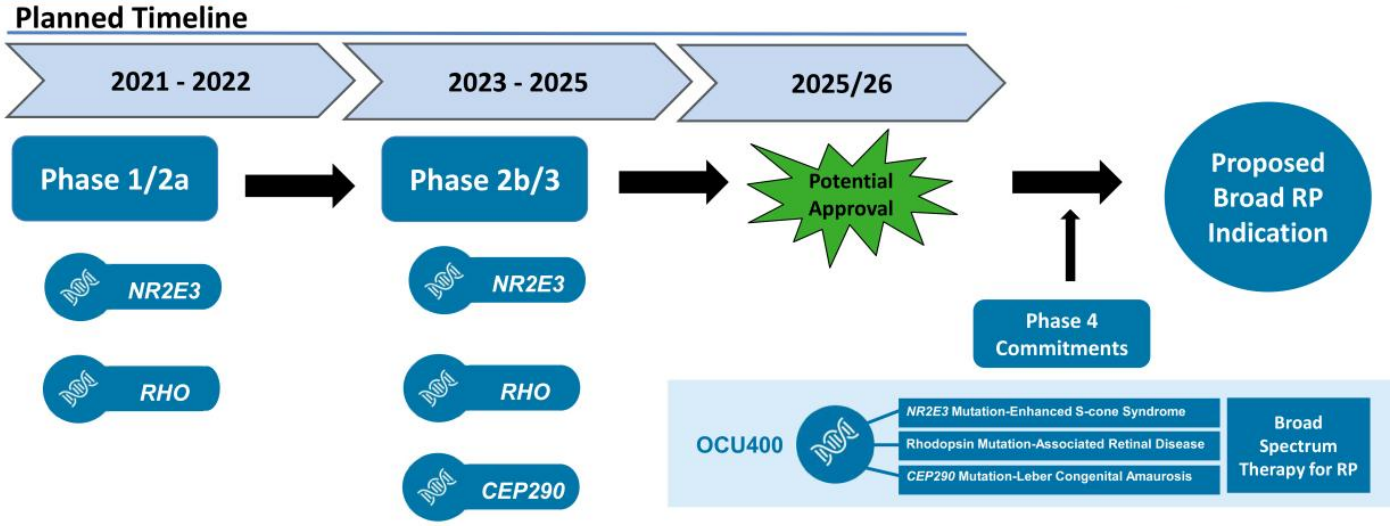
OCU400 – Demonstrated Safety in Mouse Model

Study Results Confirm Overexpression of *Nr2e3* by subretinal AAV8-*Nr2e3* Injection Is Not Detrimental to Retina – No Off-Target Effects





OCU400 – Clinical and Regulatory Strategy



- Successfully completed manufacturing at commercial scale (200L) at CanSinoBio to support clinical studies
- Preclinical tox studies in-progress
- On target to file IND in 2H21

OCU400 – Competitive Overview

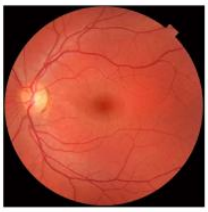
Features	OCU400	Traditional Gene Therapy	Cell Therapy
	ocugen	Roche, HORAMA, Biogen, MEIRAGTx, agtc, NOVARTIS, Allergan, SANOFI	Astellas, jCyte, ReNeuron
One product for many IRDs (including broad RP indication)	✓	✗	Limited ✓
Technology established in the ocular disease space	✓	✓	✗
POC data in RP models with different genetic mutations	✓	✗	✗
Expected long-term outcome	Potentially longer benefit due to promotion of homeostasis	Potentially limited due to loss of retinal cells over time	Not established
Target Patient Population	Large	Small (specific to mutation)	Variable
Developmental cost	Low (economies of scale)	High (No economies of scale)	High

Potential Competitors pursuing treatment of RP with Traditional Gene Therapy

Potential Competitors pursuing treatment of RP with Cell Therapy

OCU410 (AAV-*RORA*) – Dry Age-Related Macular Degeneration

We Believe OCU410 Has the Potential to Address this Disease through its Multi-Factor Approach



Normal Retina

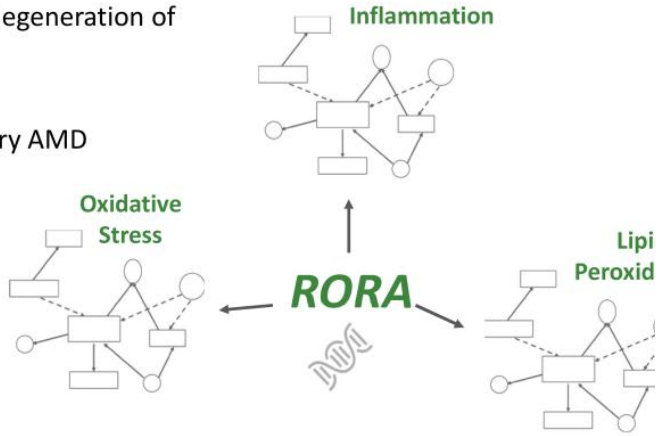
Dry AMD

- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD

Dry AMD

Contributing Factors

- Aging
- Genetics
- Environmental Factors



References: https://www.brightfocus.org/macular/article/age-related-macular-facts-figures
https://www.uniprot.org/uniprot/P35398#function
https://pubmed.ncbi.nlm.nih.gov/21998696/
https://pubmed.ncbi.nlm.nih.gov/19786043/

OCU200:

Diabetic Macular Edema (DME)
Diabetic Retinopathy (DR)
Wet Age-Related Macular Degeneration (Wet AMD

Novel Biologic Offering Benefits Beyond Anti-VEGF

OCU200 – Potential to Treat DME, DR & Wet AMD

OCU200 Provides Hope to All patients with DME, DR or Wet AMD

DME	**→ ~0.7M patients in the US***
DR	**→ ~7.7M patients in the US***
Wet AMD	**→ ~1.1M patients in the US***

~50% of Patients DO NOT Respond to Anti-VEGF/Corticosteroids Therapies

- **OCU200 is a Transferrin-Tumstatin Fusion Protein**
  - Tumstatin: Multiple MOAs for treatment and prevention of macular degeneration and neovascularizatio
  - Transferrin: Targets the site of action and improves uptake (better target engagement)
- Integrin Targeting provides hope to these patients who are non-responders to current therapies
- Distinct MOA through targeting Integrin pathways can potentially also help reduce number of injections for patients who do respond to Anti-VEGF & corticosteroids therapies
- Significant global market potential

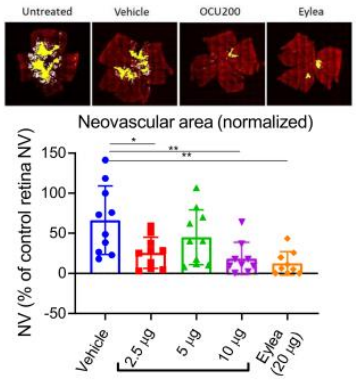
(*) https://www.gene.com/stories/retinal-diseases-fact-sheet
https://www.brightfocus.org/macular/article/age-related-macular-facts-figures

OCU200 –Transferrin-Tumstatin Fusion Protein

OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies

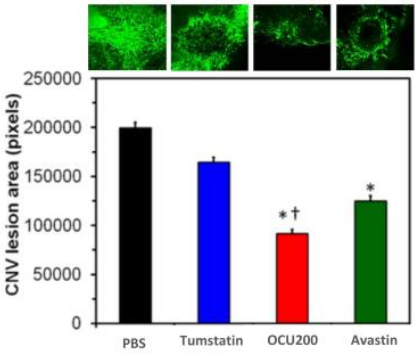
- Inhibits new blood vessel formation
- Anti-inflammatory
- Anti-oxidative

DME/DR
Oxygen-Induced Retinopathy (OIR) Mouse Model



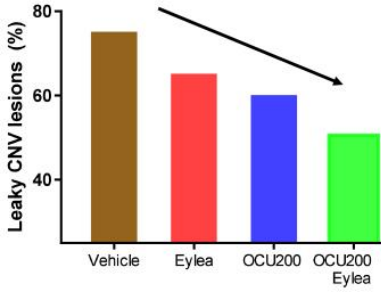
Effect of OCU200 intravitreal treatments on Neovascularization (NV). Data are presented as mean± SD. Filled circles represent data points from individual eyes
* P < 0.05, ** P < 0.01 (n = 9-10 eyes per group)

Wet AMD
In-Vivo Laser-Induced Rat CNV Model



* indicates p<0.05 when compared to PBS and/or tumstatin treatment
† indicates p<0.05 when compared to Avastin; CNV lesions measured on day 14 after treatment

Wet AMD
In-Vivo Laser-Induced Mouse CNV Mod



Data expressed as percentage of CNV lesions on Da
10 after treatment. Laser induction & treatment sta
on Day 0

OCU200 – Distinct Mechanism of Action

We believe OCU200 has the potential to become a disease modifying therapeutic for broader patient population

Features	OCU200	Anti-VEGF	Anti-Integrin
	ocugen	Genentech[1] NOVARTIS[1] REGENERON[1] KODIAK	ASCLEPIX Allegro
Reduces VEGF level/Fluid	✓	✓	✓
Selectively works on active endothelial cells (Neovascular)	✓	✗	✓
Activates native anti-angiogenic response	✓	✗	✓
Enhanced effective delivery through Transferrin	✓	✗	✗
Pro-apoptotic and anti-oxidative	✓	✗	✓
Dosing Frequency	Expected once in 3 months	1-3 months	1-3 months

Potential Competitors pursuing treatment using Anti-VEGF approach

Potential Competitors pursuing treatment using Anti-Integrin approach

(1) Approved

Key Inflection Points

- COVAXIN™ - Vaccine candidate for the US and Canadian markets with potential for revenues this year
- Ophthalmology
  - Modifier Gene Therapy Platform has the potential for one product to treat many diseases
  - Novel biologic has the potential to treat anti-VEGF /corticosteroids non-responders (~50% of the patients)
  - Multiple near and mid-term milestones with plan to initiate four Phase 1/2 trials over next 18 months

A Bold Vision to Cure Blindness Diseases and Offer a Differentiated Vaccine to Save Lives from COVID-19

For more information, contact:
IR@ocugen.com