

## Courageous Innovation

April 2022 NASDAQ: OCGN

## Forward Looking Statement

This presentation 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 gualitative 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 the data and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by the U.S. Food and Drug Administration ("FDA") or otherwise sufficient to support our Investigational New Drug applications ("IND") or planned Biologics License Applications ("BLA"), as applicable; whether the FDA will accept our IND submissions without any changes, or if we are required to submit additional information to the FDA in support of our IND submissions, the extent and significance of any such changes; the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a for COVAXIN<sup>™</sup>, including our Phase 2/3 immuno-bridging and broadening clinical trial and planned safety-bridging clinical trial; whether the FDA will authorize COVAXIN<sup>™</sup> for administration as a vaccine for pediatric uses against COVID-19 and the timing and scope of any such authorization; any additional chemistry, manufacturing, and controls information that we may be required to submit; whether and when a BLA for COVAXIN<sup>M</sup> will be submitted to the FDA; whether and when a BLA may be approved by the FDA, whether a New Drug Submission application may be approved by Health Canada, and whether the additional information that we provide to Health Canada will be sufficient to support an approval by Health Canada of COVAXIN<sup>M</sup> and any delays associated therewith; the authorizations or 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 authorized or approved, whether it will be commercially successful; whether developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, or other jurisdictions; manufacturing capabilities, manufacturing capacity, and supply restrictions, including whether sufficient doses of COVAXIN<sup>™</sup> can be manufactured or supplied 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<sup>™</sup> 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 presentation speak only as of the date of this presentation. Except as required by law, we assume no obligation to update forward-looking statements contained in presentation whether as a result of new information, future events, or otherwise, after the date of this presentation.



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

### Mission

At Ocugen, we are developing novel solutions to medical challenges, approaching healthcare innovation with purpose and agility to deliver new options for people facing disease.

### Vision

We are fostering a future where no one feels hopeless in the face of disease. From genetic disorders to new diseases, our expertise and tenacity are creating choices – for people and for global communities.



Pioneering a breakthrough modifier gene therapy for several genetic forms of vision impairment

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

### Co-developing a COVID-19 vaccine



## **Pipeline Overview**

\*\* No approved therapies exist

	Asset/Program	<b>Indication</b>	Status
Vaccine	<b>COVAXIN™ (BBV152)</b> Whole-Virion Inactivated Vaccine	COVID-19	US Phase 2/3* (Temporarily paused dosing) Health Canada NDS under review*
Modifier Gene Therapy Platform	<b>OCU400 ***</b> AAV-hNR2E3	Gene mutation-associated retinal degeneration**	
		NR2E3 Mutation	Phase 1/2
		RHO Mutation	Phase 1/2
		CEP290 Mutation	To be submitted
		PDE6B Mutation	To be submitted
	<b>OCU410</b> AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)**	Preclinical
Novel Biologic	<b>OCU200</b> Transferrin – Tumstatin	Diabetic Macular Edema	Preclinical
		Diabetic Retinopathy	Preclinical
		Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical



\* Based on Bharat Biotech-sponsored clinical trials in India \*\*\* 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)

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

# COVAXIN™ (BBV152)

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





## **Product Profile**

COVAXIN™ (BBV152): Whole Virion Inactivated SARS-CoV-2 Antigen & Adjuvant: 6ug/SHD + Algel-IMDG (TLR7/8 Agonist)



### **Proposed indication**

Prevention of COVID-19 caused by SARS-CoV-2



### **Target population**

Pediatric: 2-18 years of age Adult: 18 years of age and older



### Dose Level and Regimen

6 ug per 0.5 mL suspension; 2 Doses: Day 0 & Day 28



#### Presentation

Ten doses per vial



### Expected Shelf Life

Two years in storage conditions of 2°-8°C and

stable for six months at room temp (25°C)



## Why COVAXIN<sup>™</sup> (BBV152)?

Designed to augment our North American arsenal of vaccines against COVID-19

### DESIGNED FOR BROAD SPECTRUM IMMUNE RESPONSE

- Adult and pediatric phase 2/3 data suggest both humoral & cellular responses generated against multiple viral proteins
- Data support that the vaccine induces a Th1 response (cell-mediated immunity) which can be vital for durable protection

### RESULTS SHOW PREVENTION OF SEVERE COVID-19 DISEASE

- Phase 3 data suggest prevention of hospitalizations caused by COVID-19
- Booster dose provides robust neutralizing antibody responses against Omicron and Delta variants



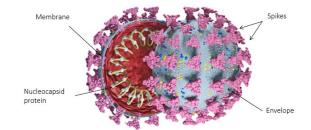
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### KNOWN SAFETY PROFILE USING VERO CELL PLATFORM

- Data demonstrate strong safety profile within adult and pediatric populations
- Technology platform used to produce Polio, Influenza and Rabies vaccines

### TRANSPORTATION AND STORAGE EASE

 10 dose vial that can be stored and shipped at 2°- 8° C with a 2-year shelf life and 6-month stability at room temperature





# Why COVAXIN<sup>™</sup> (BBV152)? The Only COVID-19 Vaccine Candidate with Clinical Results Against Delta Variant

77.8%	Overall efficacy	Adverse Events COVAXIN™ Arm	12.4%	n = 25,800 participants
93.4%	Efficacy vs severe disease	Adverse Events Placebo Arm	12.470	Participants recruited between November 2020 and January 2021 across 25 sites
65.2%	Efficacy vs B.1.617.2 (Delta)	Serious Adverse Events	<0.5%	Two doses, 28 days apart

Source: Ella, Reddy, Blackwelder, Potdar, Yadav, Sarangi et al. (2021) Efficacy, safety, and lot-to-lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial; The Lancet. Advanced online publication. https://doi.org/10.1016/S0140-6736(21)02000-6 Accessed November 11, 2021

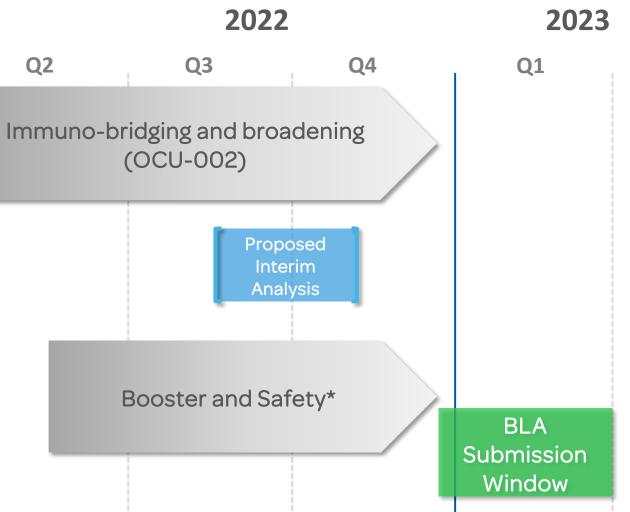


### Pathway for COVAXIN<sup>™</sup> (BBV152) in 2022 NCT: 05258669

## **OCU-002**

A Phase 2/3, Observer-Blind, Immunobridging, and Broadening Study of a Whole, Inactivated Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Vaccine (BBV152) in Healthy Adults

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	400 participants
Allocation	Randomized
Intervention Model	Parallel assignment
Intervention Model Description	1:1 randomization ratio
Primary Purpose	Prevention





# MODIFIER GENE THERAPY PLATFORM

Breakthrough technology designed to address many rare diseases as well as complex diseases that affect millions



## **Our Focus:** Nuclear Hormone Receptor Genes (NHRs)

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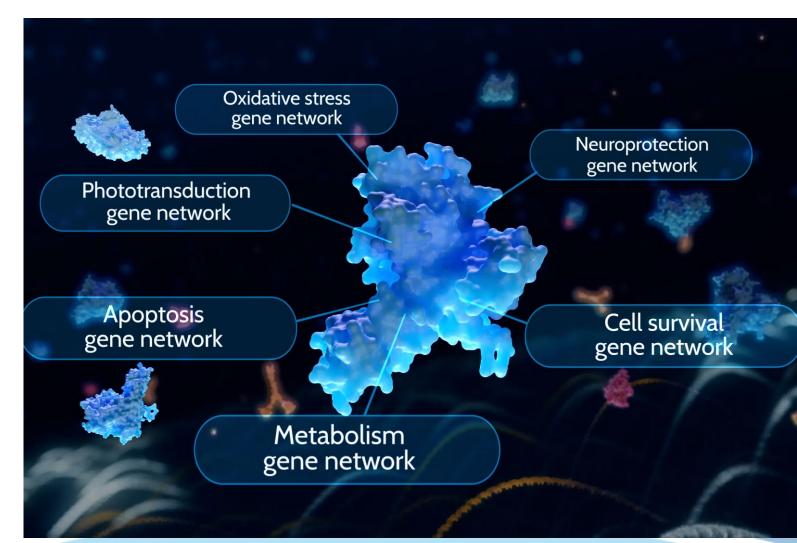
NHRs are modulators of retinal development & function, acting as "master genes" in the retina

### ~

Molecular reset of key transcription factors and associated gene networks – retinal homeostasis

### ✓

Gene modifier concept including, its impact on clinical phenotypes, is well known in other disease areas, such as cystic fibrosis and spinal muscular atrophy



### ocugen.

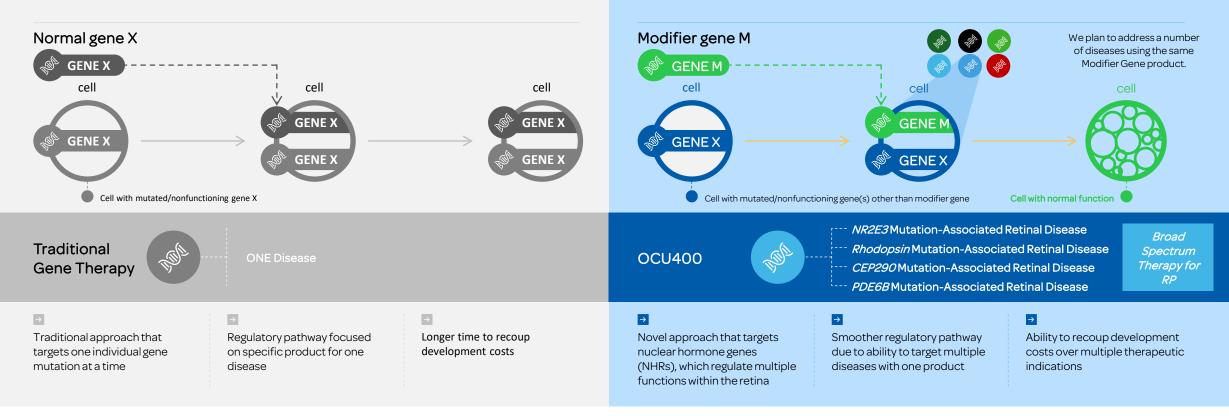
#### \*References:

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

### Our Vision: Modifier Gene Therapy vs Traditional Gene Augmentation

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

**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.





## Our Proof of Principle: 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 suggests potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and advanced stages of RP



Results suggest evidence of vision rescue in Early & Advanced Stages of disease









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

natureresearch https://www.nature.com/articles/s41434-020-0134-z



## OCU400 – Pathway to Phase 3 Clinical Trials

Just 30 days to receive FDA clearance for Phase 1/2 gene therapy clinical trial



### OCU400

A Phase 1/2 Study to Assess the Safety and Efficacy of **OCU400** for Retinitis Pigmentosa Associated With NR2E3 (Nuclear Receptor Subfamily 2 Group E Member 3) and RHO (Rhodopsin) Mutations

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	18 participants
Allocation	Non-randomized
Intervention Model:	Sequential assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment

- •NCT: 05203939
- Seven clinical trial sites being activated
- Escalation study involving low, medium, high doses
- First patient dosed by end of Q1 2022
- Periodic updates available starting in Q3 2022
- Enrollment concludes by YE 2022



## Summary of activities at Ocugen



U.S. FDA lifts clinical hold on IND submission of COVAXIN™, paving way for clinical trials supporting BLA

Temporarily paused clinical trial dosing while the Company evaluates the statements from the World Health Organization's inspection of Bharat Biotech's manufacturing facility

Comprehensive responses submitted to Health Canada against notice of deficiency



First patient dosed in Phase 1/2 clinical trial studying OCU400 for the treatment of retinitis pigmentosa resulting from genetic mutations of NR2E3 and RHO

Successfully completed manufacturing at commercial scale (200L) at CanSinoBio to support clinical studies

Expanded manufacturing agreement with CanSinoBio to include support for OCU410



## **Experienced Leadership**



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



respo CPA Bruce Forrest, MD

Jessica Crespo, CPABruce Forrest, MDChief Accounting Officer & SVP, FinanceActing Chief Medical Officer



J.P. Gabriel SVP, Technical Operations



Zara Gaudioso, SHRM-CP AVP, Human Resources, Chief of Staff



Nirdosh Jagota, PhD SVP, Regulatory Affairs, Compliance and Safety



Huma Qamar, MD, MPH, CMI AVP, Clinical Development



Mike Shine SVP, Commercial



Arun Upadhyay, PhD SVP, Research & Development



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## Thank you!

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