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): **September 13, 2023**

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 8.01 Other Events.

On September 13, 2023, Ocugen, Inc. (the "Company") issued a press release announcing a clinical study update for Retinitis Pigmentosa (RP) participants treated in the Phase 1/2 trial to assess the safety and efficacy of OCU400 for RP associated with *NR2E3* and Rhodopsin (*RHO*) mutations and Leber congenital amaurosis (LCA) with mutation(s) in the *CEP290* gene. A copy of the press release, and a presentation used by the Company with respect to the data, are filed as Exhibit 99.1 and Exhibit 99.2, respectively, herewith and incorporated herein by reference.

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 September 13, 2023.
99.2	Presentation of Ocugen, Inc.
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: September 13, 2023

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chairman, Chief Executive Officer, & Co-Founder

Ocugen Announces Positive Clinical Study Update from the Phase 1/2 Trial of OCU400, a Modifier Gene Therapy Product Candidate, for the Treatment of Retinitis Pigmentosa (RP) and Leber Congenital Amaurosis (LCA)

- *Favorable safety and tolerability profile of OCU400 investigational drug product in RP and LCA subjects to date*
- *Clinical study update suggests continued positive trends in Best-Corrected Visual Acuity (BCVA) and Multi-Luminance Mobility Testing (MLMT), as well as positive trends in Low-Luminance Visual Acuity (LLVA) among treated eyes*
- 83% (10/12) of subjects demonstrated *stabilization or improvement* in treated eye either on *BCVA or LLVA or MLMT* scores from baseline
- *Notably, 86% (6/7) of RHO* mutation subjects *experienced either stabilization of or increase in MLMT scores from baseline including a subset of 29% (2/7) that demonstrated a 3 Lux luminance level improvement*

MALVERN, Pa., September 13, 2023 (GLOBE NEWSWIRE) -- Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines, today announced a clinical study update for Retinitis Pigmentosa (RP) participants treated in the Phase 1/2 trial to assess the safety and efficacy of OCU400 for RP associated with *NR2E3* and Rhodopsin (*RHO*) mutations and Leber congenital amaurosis (LCA) with mutation(s) in the *CEP290* gene. This clinical study update is an extension of results provided by Ocugen on April 14, 2023, and includes additional subjects from the high dose group. The Company believes that OCU400—Ocugen's therapeutic approach, utilizing a proprietary modifier gene therapy platform—has the potential to be a gene-agnostic therapeutic for RP and LCA patients with inherited retinal degeneration.

"This clinical study update supports our vision to help change the lives of patients suffering from inherited retinal diseases," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "We remain dedicated to our mission of pioneering breakthroughs in biotechnology and believe that OCU400 has the potential to have an impact on the future treatment of patients with RP and LCA."

This Phase 1/2 trial is a multicenter, open-label, dose ranging study. A total of 18 subjects with vision impairment due to RP associated with *RHO* and *NR2E3* gene mutations received a unilateral subretinal injection of either a low dose (1.66×10^{10} vg/mL), medium dose (3.33×10^{10} vg/mL), or high dose (1.66×10^{11} vg/mL) of OCU400. The study profile included a diverse group of subjects aged 18-77 years old, with varied disease stages, racial and ethnic profiles, medical histories, and mutation subgroups. Ocugen further expanded this Phase1/2 trial to enroll LCA patients with *CEP290* gene mutation and pediatric patients with *NR2E3*, *RHO* and *CEP290* mutations.

Inherited retinal diseases (IRDs) such as RP and LCA encompass a group of genetic disorders that affect the retina, the light-sensitive tissue at the back of the eye. These diseases often lead to a gradual loss of vision over time and can ultimately result in blindness. Stabilization of vision is crucial for patients with IRDs due to the progressive and degenerative nature of these conditions.

Preserving remaining vision, slowing disease progression, or improving the vision can significantly impact patients' quality of life. It not only enhances the quality of life for affected individuals but also provides hope for future treatments that may ultimately lead to vision restoration. Comprehensive care, early diagnosis, and access to emerging therapies are essential components of a strategy to stabilize vision in IRD patients.

"I am gratified to see the progress we have made in our pursuit of developing a novel gene-agnostic therapy for RP and LCA. Our team's unwavering dedication to advancing modifier gene therapy research demonstrated positive preliminary clinical results that offer renewed hope to patients and their families. We remain resolute in our mission and vision to bring a bright future to those with inherited or age-related retinal diseases through courageous innovation and unwavering determination", said Dr. Arun Upadhyay, Chief Scientific Officer, Head of Research, Development and Medical at Ocugen.

This clinical study update is based on the currently available data from Phase 1 (dose-escalation: Cohort 1, 2 and 3) and the Phase 2 (open enrollment) portion of the study. The exploratory efficacy update includes data for 12 subjects who have completed a minimum of 6-month follow up. The data set comprised of 2 subjects [Cohort 1] with 12-month follow-up, 5 subjects [N=2 from Cohort 1 and N=3 from Cohort 2] with 9-month follow-up, and 5 subjects [N=2 from Cohort 3 and N=3 from Open Enrollment/Phase 2] with 6-month follow-up.

“It is an important steppingstone for Ocugen and its mission to help the nearly 1.6 million patients affected by RP and LCA worldwide. For those suffering from these IRDs, this clinical trial update provides hope. It is encouraging to see a favorable safety and tolerability profile and positive efficacy readout for OCU400 in RP patients”, said Dr. Lejla Vajzovic, Associate Professor of Ophthalmology with Tenure, Director of Duke Vitreoretinal Fellowship Program at Duke Eye Center and Duke University School of Medicine and leader in gene-therapy research.

Key efficacy outcomes from 12 subjects demonstrated:

BCVA*:*

- 83% (10/12) of subjects demonstrated stabilization or improvements in treated eyes in BCVA scores from baseline
- 42% (5/12) of OCU400 treated eyes experienced ≥4-letter improvement and 33% (4/12) treated eyes experienced ≥7-letter improvement in BCVA from baseline
- 57% (4/7) of *RHO* subjects’ treated eyes experienced ≥4-letter improvement and 43% (3/7) treated eyes experienced ≥7-letter improvement in BCVA scores from baseline

LLVA:

- 83% (10/12) of subjects demonstrated stabilization or improvement in treated eyes in LLVA scores from baseline
- 42% (5/12) of OCU400 treated eyes experienced ≥5-letter improvement (1 line) in LLVA from baseline, with 25% (3/7) increasing by ≥10 letters (2 lines)
- 43% (3/7) of *RHO* subjects experienced ≥5-letter improvement (1 line) in treated eyes in LLVA scores from baseline, among which 29% (2/7) increased by ≥10 letters (2 lines)

MLMT:

- 75% (9/12) of subjects demonstrated stabilization or improvement in treated eyes in MLMT scores from baseline
- 33% (4/12) of subjects in the low, medium, and high dose cohorts experienced at least 1 Lux luminance level improvement from baseline in treated eyes, among which 17% (2/12) increased by 3 Lux luminance levels
- 86% (6/7) of *RHO* subjects experienced either stabilization or increases in MLMT scores from baseline, among which 29% (2/7) improved by 3 lux levels

“The *RHO* mutation affects more than 10,000 people in the US,” said Dr. David Birch, Scientific Director, Retina Foundation of the Southwest and Principal investigator of the study. “In my view, the clinical study update supports the gene-agnostic mechanism of action of OCU400 in *RHO* patients. The improvements in BCVA, LLVA and MLMT in this patient population are very exciting and encouraging because stabilization alone could be considered as a treatment benefit.”

The clinical study update from the Phase 1/2 clinical trial demonstrated that OCU400 continued to be generally safe and well-tolerated in subjects across different mutations and dose levels. There were no serious adverse events (SAEs) related to the investigational product in the low and medium-dose cohorts. In the high-dose and open-enrollment cohorts, SAEs were reported for two subjects. Adverse events were mostly deemed related to the surgical procedure and resolved within a few days to weeks.

“The clinical study update released by Ocugen appears to have a tangible biological impact on Retinitis Pigmentosa associated with *NR2E3* and *RHO* mutations,” said Dr. David Boyer, Clinical Professor of Ophthalmology USC/Keck School of Medicine Los Angeles, CA and Partner, Retina Vitreous Associates Medical Group. “These findings may indicate a huge step forward in the way we approach and treat this condition. We remain optimistic and eager to continue the trial and understand the full potential of OCU400.”

Ocugen will continue to monitor long-term safety and efficacy data from the treated patients and provide additional updates.

A webcast and conference call will take place today at 8:30 a.m. ET:

Dial-in Numbers: (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers Conference ID: 7803227

Webcast: Available on the events section of the Ocugen investor site

About Modifier Gene Therapy

Modifier gene therapy is designed to fulfill unmet medical needs related to retinal diseases, including IRDs, such as RP, LCA, and Stargardt disease, as well as dry AMD. Our modifier gene therapy platform is based on the use of Nuclear hormone receptors (NHRs), master gene regulators, which have the potential to restore homeostasis — the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, we believe that our modifier gene therapy platform, through its use of NHRs, represents a novel approach that has the potential to address multiple retinal diseases caused by mutations in multiple genes with one product, and to address complex diseases that are potentially caused by imbalances in multiple gene networks. Currently Ocugen has three modifier gene therapy programs OCU400 (RP, LCA), OCU410 (dry AMD), OCU410ST (Stargardt disease).

About OCU400

OCU400 is the Company’s gene-agnostic modifier gene therapy product based on NHR gene, *NR2E3*. *NR2E3* regulates diverse physiological functions within the retina—such as photoreceptor development and maintenance, metabolism, phototransduction, inflammation and cell survival networks. Through its drive functionality, OCU400 resets altered/affected cellular gene-networks and establishes homeostasis—a state of balance, which has the potential to improve retinal health and function in patients with inherited retinal diseases.

About Ocugen, Inc.

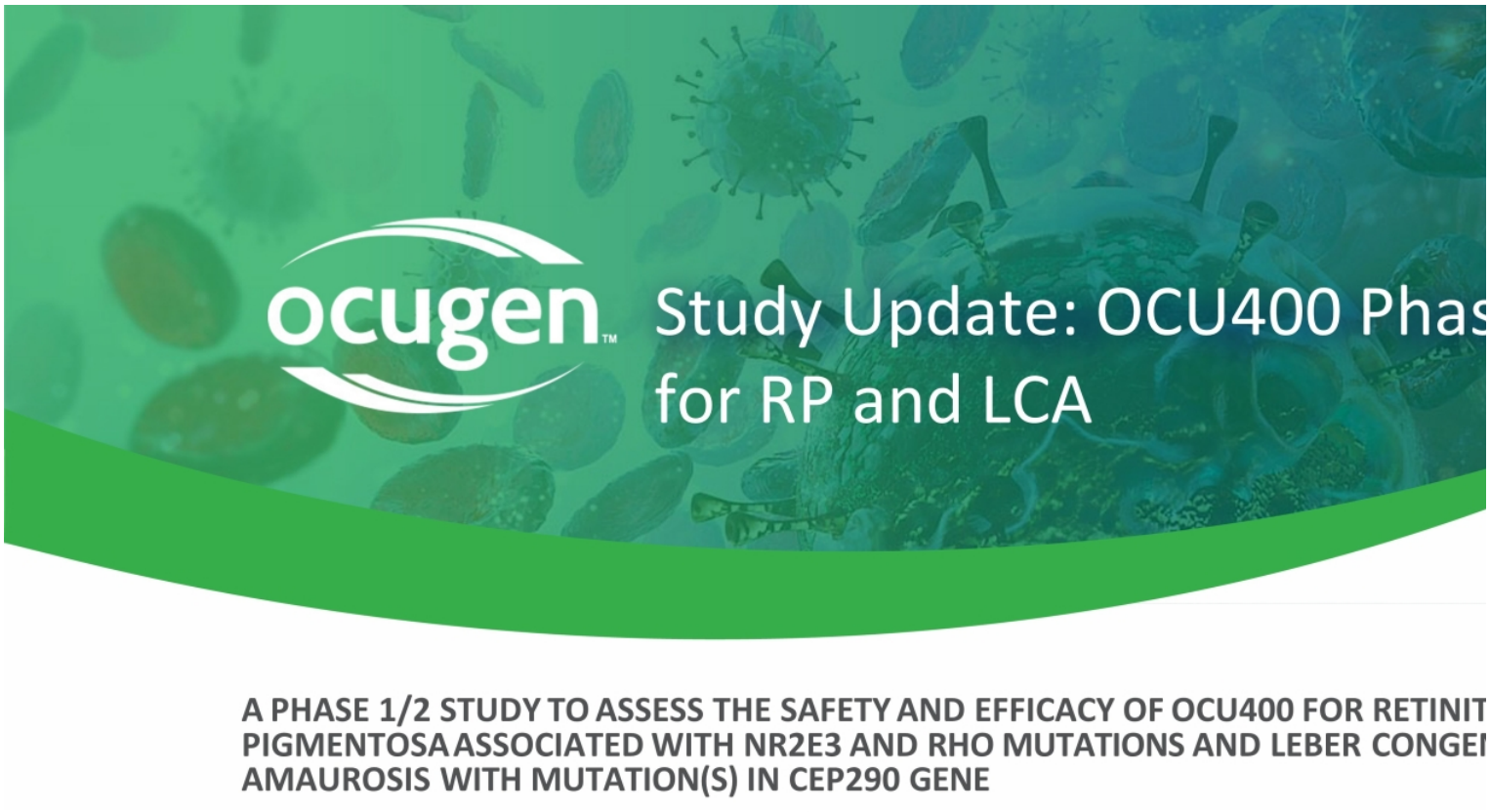
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patients’ lives through courageous innovation—forging new scientific paths that harness our unique intellectual and human capital. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with a single product, and we are advancing research in infectious diseases to support public health and orthopedic diseases to address unmet medical needs. Discover more at www.ocugen.com and follow us on Twitter and LinkedIn.

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, including, but not limited to, statements regarding qualitative assessments of available data, potential benefits, expectations for ongoing clinical trial results, and anticipated timing of clinical trial updates and regulatory interactions. . 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, including, but not limited to, the risks that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; that unfavorable new clinical trial data may emerge in the Phase 1/2 clinical trial or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive of the results or success of later clinical trials; and that that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities. 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.

Contact:
Tiffany Hamilton
Head of Communications
Tiffany.Hamilton@ocugen.com

Exhibit 99.2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Study Update: OCU400 Phas
for RP and LCA
A PHASE 1/2 STUDY TO ASSESS THE SAFETY AND EFFICACY OF OCU400 FOR RETINIT
PIGMENTOSA ASSOCIATED WITH NR2E3 AND RHO MUTATIONS AND LEBER CONGEI
AMAUROSIS WITH MUTATION(S) IN CEP290 GENE

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Re which are subject to risks and uncertainties, including, but not limited to, statements regarding qualitative asses data, potential benefits, expectations for ongoing clinical trial results, and anticipated timing of clinical trial upda interactions. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continu "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," or other words that conve future events or outcomes to identify these forward- looking statements. Such statements are subject to numer factors, risks, and uncertainties that may cause actual events or results to differ materially from our current exp but not limited to, the risks that preliminary, interim and top-line clinical trial results may not be indicative of, ar final clinical data; that unfavorable new clinical trial data may emerge in the Phase 1/2 clinical trial or through fu existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive of the re later clinical trials; and that that clinical trial data are subject to differing interpretations and assessments, includ authorities. These and other risks and uncertainties are more fully described in our periodic filings with the Secu Commission (SEC), including the risk factors described in the section entitled "Risk Factors" in the quarterly and we file with the SEC. Any forward-looking statements that we make in this presentation speak only as of the dat presentation. Except as required by law, we assume no obligation to update forward-looking statements contair presentation whether as a result of new information, future events, or otherwise, after the date of this presenta

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OCU400: A Novel Gene-Agnostic Modifier Gene Therapy for RP and LCA

FDA granted expanded Orphan Drug Designations for all retinitis pigmentosa (RP) and Leber congenital amaur (LCA) mutations

Despite its high prevalence, RP and LCA patients have limited treatment options

- US: RP & LCA affect 110,000 and 15,000 people, respectively
- Worldwide: conditions affect approximately 1.6M people

Current approved and in-development gene therapies focus on individual gene

- More than 125 mutated genes associated with RP and LCA
- Developing a single therapy to treat each mutation is not feasible and a daunting task

OCU400 addresses shortcomings of current gene therapy approaches

- Broad-spectrum, gene-agnostic approach to genetically diverse inherited retinal diseases
- Consists of human Nuclear Hormone Receptor gene, ***NR2E3***, ***with potential to preserve/improve/restore re function***
- Being developed as one-time, curative therapy with a ***single*** sub-retinal injection, using *NR2E3*

Dose escalation and recruitment of RP patients completed

- High dose established as Maximum Tolerable Dose (MTD)
- Continue to enroll patients with LCA and Pediatric patients
- Intend to initiate a Phase 3 trial near the end of 2023/early 2024*

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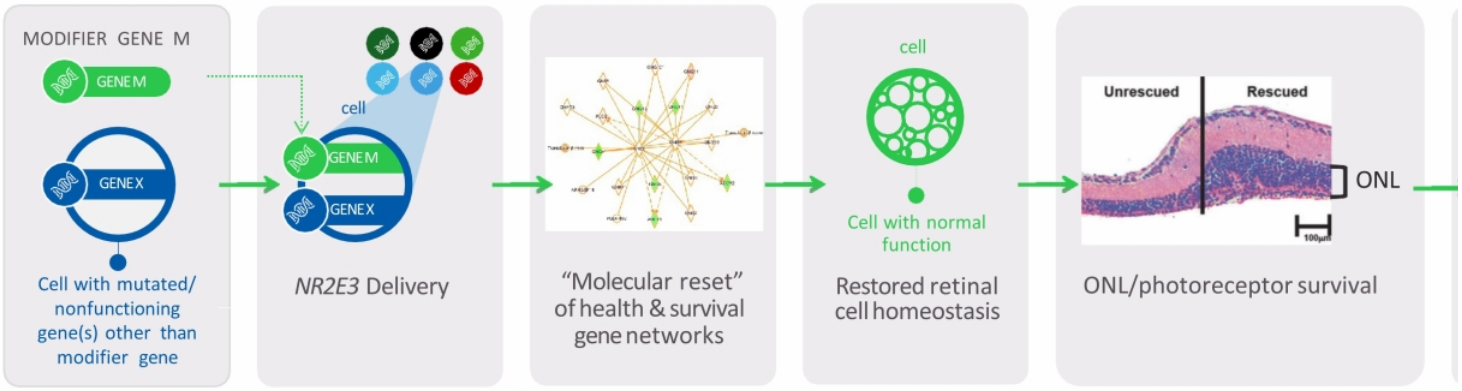
* Depends on FDA alignment on Phase 3 clinical development plan

Modifier Gene Therapy: A Broader Reach

Gene modifier therapy can potentially address multiple genetic defects with a single product utili
agnostic approach.

In patients with IRDs, this could mean:



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OCU400 Clinical Program

A Phase 1/2 Study to Assess the Safety and Efficacy of OCU400 for Retinitis Pigmentosa associate
and *RHO* mutations and Leber Congenital Amaurosis with mutation(s) in *CEP290* gen

Primary: Safety

- Safety of subretinal administration of OCU400
- Immune responses
- Systemic Distribution

Exploratory: Efficacy

- Best Corrected Visual Acuity (BCVA)
- Low Luminance Visual Acuity (LLV
- Multi-Luminance Mobility Test (ML

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Clinical Trials.gov Identifier: **NCT05203939**

Key Inclusion/Exclusion Criteria

Inclusion

- Males or females ≥18 years (Adult) / 6-17 years (Pediatric)
- Confirmed genetic diagnosis of AR-*NR2E3* mutations or AD-*NR2E3* mutation Or *RHO* mutations or *CEP290* mutation
- For RP Subjects: BCVA ≤ 20/50 or visual field less than 20° in any meridian, as measured by a III4e isopter or equivalent in study eye
- For LCA subjects: Best corrected visual acuity (BCVA) equal to or worse than LogMAR +0.7 but equal to or better than LogMAR 3.5

Exclusion

- For RP: Subject lacks evidence of outer spectral-domain optical coherence ton
- For LCA: Subjects with any symptoms system involvement/disease that impa function ability
- Previous treatment with a gene-thera therapy product
- Any contraindications for subretinal ir
- Cataract surgery within 3 months

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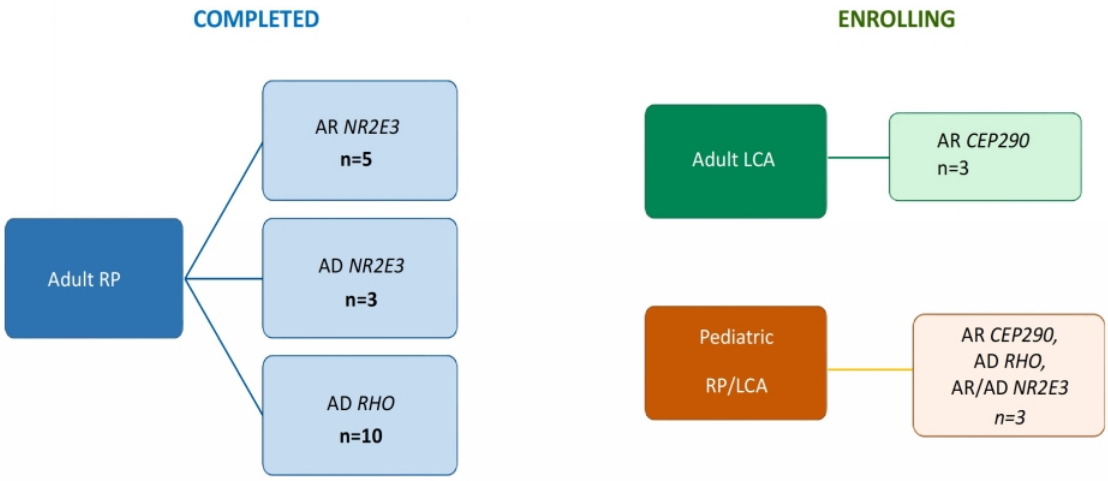
Clinical Trials.gov Identifier: **NCT05203939**

Enrollment Status



- Subjects (N=18) with ages ranging 18-77 years enrolled in this study to date
- Consists of 10 RHO subjects, 5 Autosomal Recessive NR2E3 and 3 Autosomal Dominant NR2E3 subjects
- Sub-retinal injection was mostly around the central region (and few subjects with centra temporal, superior-temporal regions)

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Safety Summary for OCU400

- The Phase 1/2 clinical trial demonstrated that OCU400 continued to be generally safe and well-tolerated in subjects across different mutations a dose levels
- There were no serious adverse events (SAEs) related to the investigation product in the low and medium dose cohorts
- In the high dose and open-enrollment cohorts, SAEs were reported for tv subjects. None of them were related to the study drug.
- Adverse events were mostly deemed related to the surgical procedure ar resolved within few days to weeks

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RP and LCA- Unmet need and Treatment Benefit Target

- IRDs, such as RP and LCA, are a group of heterogenous genetic disorders that affect
  retina, the light-sensitive tissue at the back of the eye
- They often lead to a gradual loss of vision over time and can ultimately result in blin
- ***Stabilization of vision is crucial*** for patients with RP and LCA due to the progressive degenerative nature of these diseases
- ***Preservation of remaining vision, slowing disease progression, or improving the vi***
  can significantly impact patients' quality of life. Such outcomes not only can enhanc
  quality of life for affected individuals but also provide hope that future treatments c
  ultimately lead to vision restoration.
- Comprehensive care, early diagnosis, and access to emerging therapies are essentia
  components of a ***strategy to stabilize vision in RP and LCA patients***

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Responder Analyses

- Assessed for subjects who have completed a minimum of 6-months follow-up post-OCU400 dosing

  - Improvement in Best-Corrected Visual Acuity (BCVA) from Baseline
    ≥ 4 Letters, and ≥ 7 Letters

  - Improvement in (Low Luminance Visual Acuity) LLVA from Baseline
    ≥ 5 Letters and ≥ 10 Letters

  - Improvement in (Multi-Luminance Mobility Test) MLMT from
    ≥ 3 Lux Levels, ≥ 1 Lux Level, ≥ 0 Lux Level/Ceiling Effect

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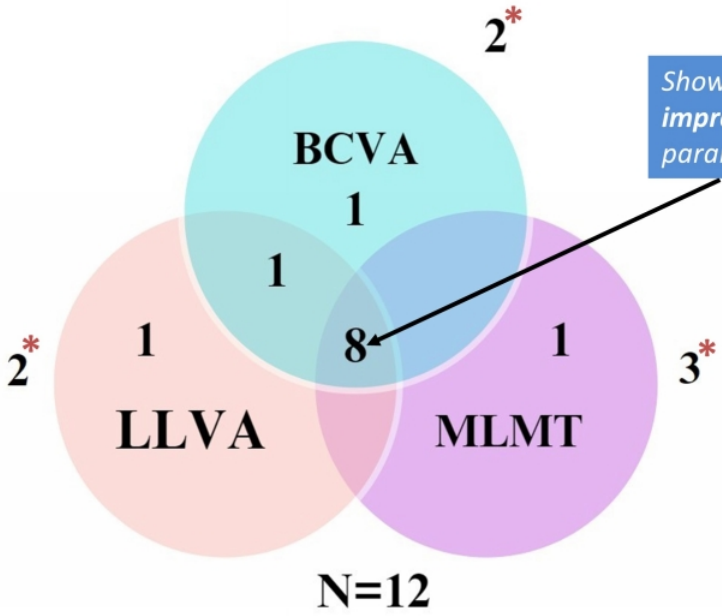
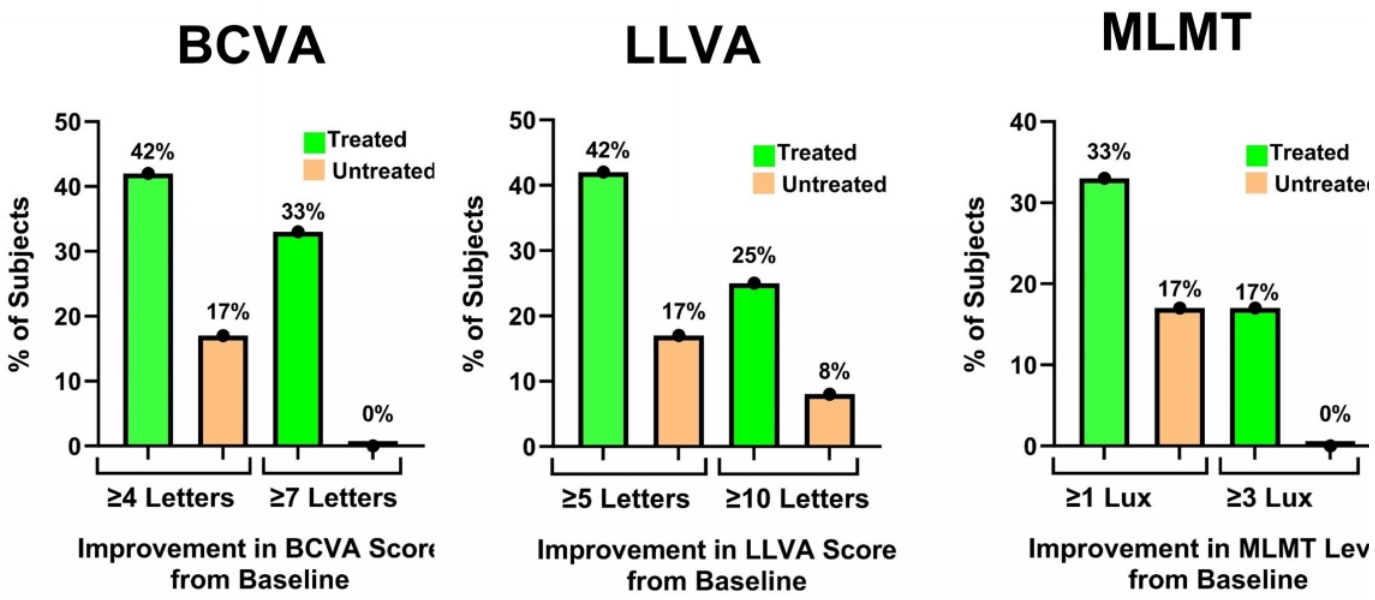
Responder Analysis

Stabilization/Improvement from Baseline [Treated Eyes]



* Non responder

Responder Analysis



Conclusions

- OCU400 continues to demonstrate favorable safety and tolerability profile of OCU400 investigational drug product in Phase 1/2 study
- Clinical study update suggests ***continued positive trends*** in Best-Corrected Visual Acuity (and Multi-Luminance Mobility Testing (MLMT), as well as positive trends in Low-Luminar Visual Acuity (LLVA) among treated eyes
- 83% (10/12) of subjects demonstrated ***preservation or improvement*** in the treated eye e on ***BCVA or LLVA or MLMT*** scores from baseline
- 75% (9/12) of subjects *demonstrated* ***stabilization or improvement*** in treated eyes in M scores from baseline
- 86% (6/7) *of RHO* mutation subjects experienced *either stabilization or increase in MLMT* from baseline, among which 29% (2/7) demonstrated **3 Lux** luminance level improvemer
- Treatment effect in *RHO* patients supports the gene-agnostic mechanism of action of OC

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Key Takeaways

- The Phase 1/2 clinical trial demonstrated that OCU400 continued to be generally saf well-tolerated in subjects across different mutations and dose levels

- Our study supports the gene-agnostic mechanism of action of the drug and demonstrates positive trends for key efficacy outcome measures like Best-Correcte Visual Acuity, Low-Luminance Visual Acuity, and Multi-Luminance Mobility testing parameters

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Acknowledgements

We would like to thank the study investigators, study participants, site coordin
and research teams.

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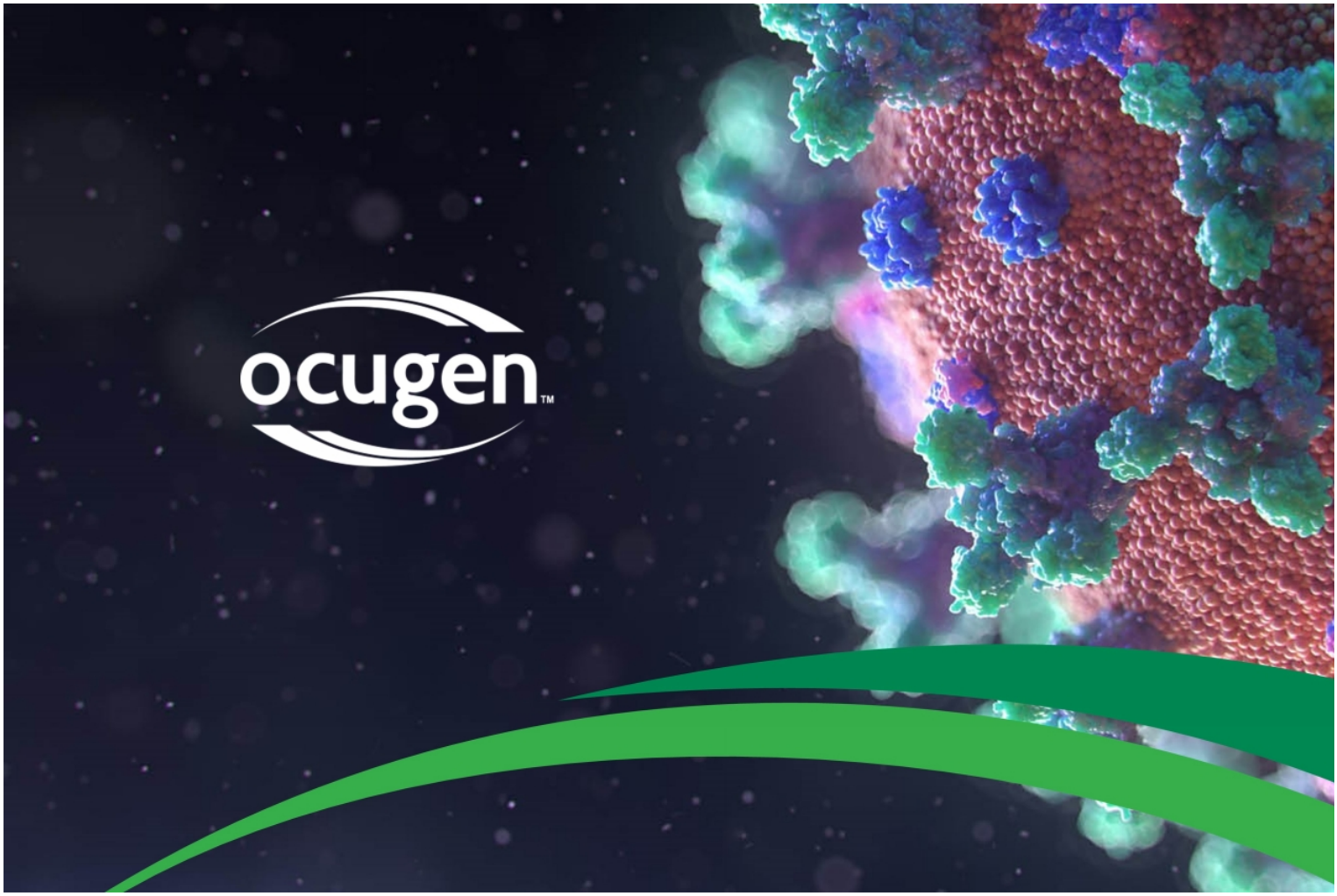
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