

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

---

**FORM 6-K**

---

**REPORT OF FOREIGN ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Month of May 2023**

**(Commission File No. 001-41636)**

---

**Oculus Holding AG**  
**(Translation of registrant's name into English)**

---

**Bahnhofstrasse 7  
CH-6300  
Zug, Switzerland**  
**(Address of registrant's principal executive office)**

---

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

---

---

## INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On May 22, 2023, Oculis Holding AG (the “Company”) issued a press release announcing positive topline results from Stage 1 of the DIAMOND Phase 3 trial in Diabetic Macular Edema with OCS-01 eye drops and held a conference call. Topical OCS-01 met the primary and secondary endpoints in Stage 1 with robust statistical significance. The primary endpoint was mean change in BCVA compared to baseline at Week 6. OCS-01 showed a statistically significant improvement in BCVA over baseline compared to vehicle (OCS-01: 7.2 letters vs vehicle: 3.1 letters,  $p=0.007$ ). This effect was sustained to Week 12 with statistical significance (OCS-01: 7.6 letters vs vehicle: 3.7 letters,  $p=0.016$ ). The Company also observed a higher percentage of patients in the OCS-01 group who achieved  $\geq 15$ -letter improvement in BCVA from baseline vs vehicle at Week 6 (OCS-01: 25.3% vs vehicle: 9.8%,  $p=0.015$ ), which was sustained to Week 12 (OCS-01: 27.4% vs vehicle 7.5%,  $p=0.009$ ). The effect on retinal thickness was also observed with a statistically significant decrease in CST at Week 6 vs baseline in the OCS-01 treatment arm (OCS-01:  $-63.6 \mu\text{m}$  vs vehicle:  $+5.5 \mu\text{m}$ ,  $p<0.0001$ ). The decrease in retinal thickness persisted to Week 12 ( $-61.6 \mu\text{m}$  vs  $-16.0 \mu\text{m}$ ,  $p=0.004$ ). OCS-01 was well tolerated, with no unexpected adverse events observed. The OCS-01 development program will continue as planned with Stage 2 which includes two global trials, each enrolling approximately 350-450 patients. The Company expects to begin Stage 2 of the DIAMOND trial in the second half of this year. Enclosed hereto are copies of the press release and related investor presentation, which is also available on the Company’s website.

The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, is intended to be 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

### EXHIBIT INDEX

| <b>Exhibit</b> | <b>Description</b>               |
|----------------|----------------------------------|
| 99.1           | Press Release dated May 22, 2023 |
| 99.2           | Investor Presentation            |

---

**SIGNATURES**

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, thereunto duly authorized.

Date: May 22, 2023

**OCULIS HOLDING AG**

By: /s/ Sylvia Cheung  
Sylvia Cheung  
Chief Financial Officer



### Oculis Announces Positive Top Line Results from DIAMOND Stage 1 Phase 3 Trial in Diabetic Macular Edema with OCS-01 Eye Drops

- *DIAMOND trial in Diabetic Macular Edema (DME) with topical OCS-01 met its stage 1 objective of validating the loading and maintenance dosing regimen designed to optimize OCS-01 efficacy potential with robust statistical significance*
- *Primary efficacy endpoint of mean change in Best Corrected Visual Acuity (BCVA) versus baseline at Week 6 showed statistically significant increase in visual acuity in the OCS-01 arm compared to vehicle arm*
- *Statistically significant secondary endpoints showed higher percentage of patients achieving  $\geq 15$ -letter improvement in BCVA and better improvement in retinal thickness in the OCS-01 arm versus vehicle arm*
- *OCS-01 was well-tolerated with no unexpected adverse events observed*
- *If approved, OCS-01 has the potential to become the first topical and non-invasive treatment for DME*
- *An investor and analyst call will be held today at 8:00am US Eastern Time, details below*

**ZUG, Switzerland, and BOSTON, USA, May 22, 2023** – Oculis Holding AG (Nasdaq: OCS) (“Oculis”), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced positive top line results from Stage 1 of its Phase 3 DIAMOND trial of OCS-01 eye drops in Diabetic Macular Edema (DME). DME is the leading cause of visual loss and legal blindness in patients with diabetes, affecting around 37 million people worldwide, with a significant number of patients left untreated due to a lack of convenient treatment options.

### OCS-01 Positive Phase 3 Stage 1 Top Line Results Could Signify a Paradigm Shift in DME

DIAMOND (DIAbetic Macular edema patients ON a Drop) is a Phase 3, two-stage, double-masked, randomized, multi-center trial to assess the efficacy and safety of OCS-01 eye drops in DME patients. The primary objective of Stage 1 was to select the optimal dosing regimen. Stage 1 was conducted in 39 sites across the USA and Europe with 148 patients randomized 2:1 to receive OCS-01 (n=100) or vehicle (n=48) six times daily for a six-week loading phase and then three times daily for a subsequent six-week maintenance phase.

Stage 1 met the primary efficacy endpoint with a statistically significant improvement in mean BCVA “Early Treatment Diabetic Retinopathy Study” chart (BCVA ETDRS) score from baseline to Week 6 versus (vs) vehicle (OCS-01: 7.2 letters vs vehicle: 3.1 letters,  $p=0.007$ ) demonstrating strong visual gain in the treatment arm. The effect was sustained to Week 12 with statistical significance (OCS-01: 7.6 letters vs vehicle 3.7 letters,  $p=0.016$ ). Furthermore, there was a higher percentage of patients in the OCS-01 group who achieved  $\geq 15$ -letter improvement in BCVA from baseline vs vehicle at Week 6 (OCS-01: 25.3% vs vehicle: 9.8%,  $p=0.015$ ), which was sustained to Week 12 (OCS-01: 27.4% vs vehicle 7.5%,  $p=0.009$ ).

---

OCS-01, in this 3-month trial, has met both clinical efficacy endpoints (main BCVA change, proportion of patients with 3 lines gain) that are required for regulatory approval, if met at 12 months treatment duration.

An effect on retinal thickness was also observed with a statistically significant decrease in Central Subfield Thickness (CST) at Week 6 versus baseline in the OCS-01 treatment arm (OCS-01: -63.6  $\mu\text{m}$  vs vehicle: +5.5  $\mu\text{m}$ ,  $p < 0.0001$ ). The decrease in retinal thickness persisted to Week 12 (-61.6  $\mu\text{m}$  vs -16.0  $\mu\text{m}$ ,  $p = 0.004$ ).

OCS-01 was well-tolerated with no unexpected adverse events observed.

The OCS-01 development program will continue as planned with Stage 2 which includes two global trials, each enrolling approximately 350-450 patients. Oculis expects to begin Stage 2 of the DIAMOND trial in the second half of this year.

**Riad Sherif M.D., CEO of Oculis, said:** *“I am pleased and very encouraged that in Stage 1 of this trial, OCS-01 has met both primary and secondary endpoints in a robust and statistically significant manner. A topical agent has never demonstrated a positive result in DME. Now, OCS-01 has been validated in two different studies with consistent and repeated positive results. We remain focused on advancing with high priority the DIAMOND Phase 3 trial to Stage 2. This important milestone brings us one step closer to providing the first treatment in the form of eye drops to patients with DME which is a devastating and blinding disease.”*

**Arshad M. Khanani, M.D., M.A, Director of Clinical Research at Sierra Eye Associates and Clinical Associate Professor at University of Nevada, Reno School of Medicine, Reno, Nevada and Co-Principal Investigator for the DIAMOND trial, commented:** *“As a co-principal investigator of the Phase 3 DIAMOND trial, it is exciting to see the positive Stage 1 results from this trial. A 7.2 letters improvement in BCVA and a 63.6  $\mu\text{m}$  reduction in CST at 6 weeks after initiating topical treatment with OCS-01 in patients with DME is clinically meaningful for treating physicians and patients. As a non-invasive treatment that has shown these positive results, OCS-01 has the potential of benefitting a large number of patients with DME if approved. I am looking forward to enrolling patients in Stage 2 of this trial.”*

**David S. Boyer, M.D., Adjunct Clinical Professor of Ophthalmology, Keck School of Medicine, University of Southern California, Los Angeles and Co-Principal Investigator for the DIAMOND trial, said:** *“The mechanism of DME involves both increased permeability and inflammation. Current anti-VEGFs are effective as anti-permeability agents but have no effect on inflammation. Therefore, a significant proportion of patients are sub-optimally treated with anti-VEGFs alone. If approved, OCS-01 has the potential to complement current treatment and address recalcitrant patients. Furthermore, since it is a topical agent, it has also the potential to be a first line treatment in DME, if approved. In short, I believe the impact of OCS-01 in DME could be a true game-changer.”*

#### **About OCS-01 eye drops and the OPTIREACH® technology**

Leveraging Oculis' proprietary Optireach® technology, OCS-01 is a novel, high concentration (15 mg/ml), topical formulation of dexamethasone. It is developed to reach the retina via an eye drop, a route of administration for DME that is in contrast with currently available therapies, all requiring the use of more invasive treatments such as ocular implants or intravitreal injections to deliver the medication to the retina. The Optireach® solubilizing formulation technology addresses the main limitations of conventional eye drops by improving the solubility of lipophilic drugs, increasing the residence time on the eye surface and thereby, enabling the drug passage from the eye surface to the posterior segment of the eye.

#### **About Diabetic Macular Edema (DME)**

DME is the leading cause of visual loss and legal blindness in patients with diabetes. Currently, it is estimated to affect around 37 million people worldwide and, with the rise of diabetes, the prevalence is expected to increase to 53 million by 2040<sup>1,2</sup>. DME is an irreversible and progressive complication of

---

diabetic retinopathy and is related to consistently high blood sugar levels that damage nerves and blood vessels in the macula, the area of the retina responsible for sharp vision. DME occurs when blood vessels in the retina swell, and then leak, leading to a fluid build-up (edema) into the retina. There remains a significant need for safer, more effective, longer lasting, and less burdensome treatments for DME patients.

### **Analyst and Investor Call**

The Oculis management team will host an analyst and investor call on Monday, May 22nd at 8:00 am US Eastern Time to discuss the news. During the event, the Oculis management team will present the results of Stage 1, **Pravin Dugel, M.D.** (USA) will moderate questions and both co-principal investigators for the DIAMOND trial, **Arshad M. Khanani, M.D.** (USA) and **David S. Boyer, M.D.**, (USA) will be present to answer clinical questions during the live Q&A session.

To access the live event online, please pre-register for the webinar here. To access the live event by phone, please pre-register for the conference call here. A replay of the webinar and accompanying slides will be available for 90 days following the event through the “Events and Presentations” page of the “Investors and Media” section of the company’s website.

**-ENDS-**

### **About Oculis**

Oculis (Nasdaq: OCS) is a global biopharmaceutical company purposefully driven to save sight and improve eye care. Oculis’ highly differentiated clinical-stage pipeline comprises multiple innovative product candidates in development for eye diseases of high unmet need. It includes OCS-01 eye drops, a topical candidate in Phase 3 development for diabetic macular edema (DME) and inflammation and pain following ocular surgery; OCS-02 eye drops, a topical biologic candidate in Phase 2 development for dry eye disease (DED) and uveitis; and OCS-05, a disease modifying candidate for acute optic neuritis (AON) and other neuro-ophthalmic disorders, such as glaucoma, diabetic retinopathy, geographic atrophy, and neurotrophic keratitis. The first in-patient, proof-of-concept trial with OCS-05 is currently ongoing in France. Headquartered in Switzerland and with operations in the US, Europe, and China, Oculis’ goal is to deliver life-changing eye treatments to patients worldwide. The company is led by an experienced management team with a successful track record in the pharmaceutical industry, supported by leading international healthcare investors.

For more information, please visit: [www.oculis.com](http://www.oculis.com)

(1) *Yau et al. Global Prevalence and Major Risk Factors of Diabetic Retinopathy, Diabetes Care 2012 Mar; 35(3): 556-564*

(2) *International Diabetes Federation – [diabetesatlas.org](http://diabetesatlas.org) Estimated diabetes prevalence worldwide in 2021: 537m, reaching 783m in 2045*

### **Contacts**

#### **Investor Relations**

LifeSci Advisors  
Corey Davis, Ph.D.  
[cdavis@lifesciadvisors.com](mailto:cdavis@lifesciadvisors.com)  
+1-212-915-2577

#### **Media Relations**

Consilium Strategic Communications  
Amber Fennell, Tracy Cheung, David Daley  
[oculis@consilium-comms.com](mailto:oculis@consilium-comms.com)

---

### **Cautionary Statement Regarding Forward Looking Statements**

This press release contains forward looking statements and information. For example, statements regarding the potential benefits of OCS-01, including patient impact and market opportunity; expectations for Stage 2 of the DIAMOND trial; the potential for OCS-01 to become the first topical and non-invasive treatment for DME; the potential for OCS-01 to complement anti-VEGF treatment; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical and preclinical studies; Oculis' research and development programs, regulatory and business strategy, future development plans, and management; Oculis' ability to advance product candidates into, and successfully complete, clinical trials; and the timing or likelihood of regulatory filings and approvals, are forward looking. All forward looking statements are based on estimates and assumptions that, while considered reasonable by Oculis and its management, are inherently uncertain and are inherently subject to risks, variability and contingencies, many of which are beyond Oculis' control. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. The clinical data presented herein is preliminary and is subject to change, as analysis is ongoing. These results may not be reproduced in subsequent patients and clinical trials. All forward-looking statements are subject to risks, uncertainties and other factors that may cause actual results to differ materially from those that we expected and/or those expressed or implied by such forward-looking statements. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of Oculis, including those set forth in the Risk Factors section of Oculis' filings with the U.S. Securities and Exchange Commission (the "SEC"). Copies of these documents are available on the SEC's website, [www.sec.gov](http://www.sec.gov). Oculis undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.



Oculis

## Rethinking Ophthalmology

OCS-01 | DIAMOND Trial - DME Phase 3 Stage 1 Results  
May 22, 2023



This presentation is made pursuant to Section 5(d) and/or Rule 163B of the Securities Act of 1933, as amended, and is intended solely for investors that are qualified institutional buyers or certain institutional accredited investors solely for the purposes of familiarizing such investors with Oculus Holding AG and determining whether such investors might have an interest in a securities offering contemplated by Oculus Holding AG. Any such offering of securities will only be made by means of a registration statement (including a prospectus) filed with the U.S. Securities and Exchange Commission, after such registration statement becomes effective. No such registration statement has been filed, or become effective, as of the date of this communication. This communication shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

These slides and the accompanying oral presentation contain forward-looking statements and information. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward-looking statements. For example, all statements we make regarding the initiation, timing, progress and results of our preclinical studies, our clinical studies, our research and development programs, our regulatory strategy, our future development plans, our ability to advance product candidates into, and successfully complete, and the timing or likelihood of regulatory filings and approvals and statements regarding the potential therapeutic benefits and market opportunities of our product candidates are forward looking. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. The clinical data presented herein is preliminary and is subject to change. These results may not be reproduced in subsequent patients and clinical trials. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: the possibility that Oculus may be adversely affected by economic, business, and/or competitive factors; Oculus' estimates of expenses and profitability; Oculus' ability to develop, manufacture and commercialize the product candidates in its pipeline; actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; the ability of Oculus or its partners to enroll and retain patients in clinical studies; the ability of Oculus or its partners to gain approval from regulators for planned clinical studies, study plans or sites; Oculus' ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; the success of Oculus' current and future collaborations, joint ventures, partnerships or licensing arrangements; the ongoing and evolving COVID-19 pandemic on Oculus' business, financial position, strategy and anticipated milestones; and other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Oculus may from time to time file or furnish with the SEC. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

This presentation and information contained herein constitutes confidential information and is provided to you on the condition that you agree that you will hold it in strict confidence and not reproduce, disclose, forward or distribute it in whole or in part and is intended for the recipient hereof only.

*Copyright of this presentation is owned by Oculus. No part of this presentation may be reproduced in any manner without the permission of Oculus.*

# Agenda

- 01** Opening Remarks **Sylvia Cheung**  
Chief Financial Officer

---
- 02** OCS-01 Phase 3 DIAMOND Stage 1 **Riad Sherif, M.D.**  
Chief Executive Officer

---
- 03** Q&A Session **David Boyer, M.D.**, Keck School of Medicine (USC); Co-PI for DIAMOND Study  
**Moderated by:** **Arshad Khanani, M.D., M.A.**, Sierra Eye Associates, University of Nevada; Co-PI for DIAMOND Study  
**Pravin Dugel, M.D.**, Director **Riad Sherif, M.D.**, Chief Executive Officer  
**Sylvia Cheung**, Chief Financial Officer

---
- 04** Concluding Remarks **Riad Sherif, M.D.**  
Chief Executive Officer

---



Oculis

## Rethinking Ophthalmology

OCS-01 | DIAMOND Trial - DME Phase 3 Stage 1 Results

May 22, 2023

# Ph 3 Stage 1: OCS-01 Eye Drops for DME Meets Primary Endpoint

Rapid and sustained improvements in vision and anatomic structure with robust statistical significance

## Primary Objective Achieved

- Results validated loading and maintenance regimen to optimize OCS-01 efficacy potential in DME

## Met Primary and Secondary Endpoints with Robust Statistical Significance

### Primary Endpoint:

- Mean change in BCVA letter score at week 6:
  - **+7.2** with OCS-01 vs. **+3.1** with vehicle (**p = 0.007**)

### Secondary Endpoints:

- Percentage with  $\geq 3$ -line (15 letter) gain in BCVA at week 6:
  - **25.3%** with OCS-01 vs. **9.8%** with vehicle (**p = 0.015**)
- Mean change in CST at week 6:
  - **-63.6  $\mu\text{m}$**  with OCS-01 vs. **+5.5  $\mu\text{m}$**  with vehicle (**p < 0.0001**)

All differences maintained or improved at week 12

No unexpected safety findings

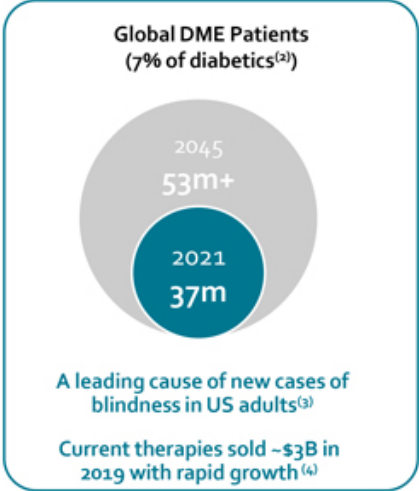
## Next Step: Phase 3 Stage 2

- Two global, 52-week Phase 3 trials commencing in 2H 2023; N = 350-450 for each
- Designed to support NDA for OCS-01 as treatment for DME

# DME is a Large and Growing Market with Critical Unmet Needs

OCS-01 Eye Drops: potential to expand pool of treated DME patients & improve outcomes for those currently treated

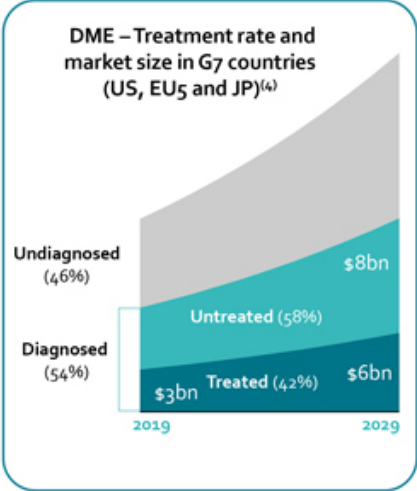
## Growing DME patient population size<sup>(1)</sup>



## Only invasive treatments approved

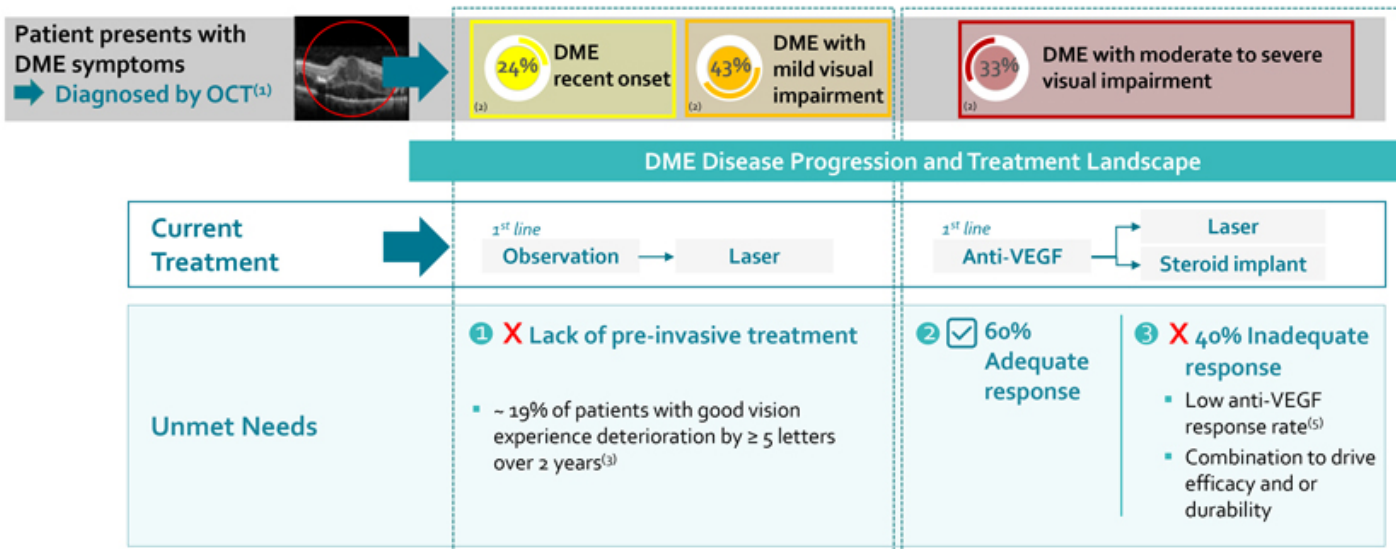


## Late start of treatment



<sup>(1)</sup> International Diabetes Federation – diabetesatlas.org Estimated diabetes around the world in 2021: 537m, reaching 783m in 2045  
<sup>(2)</sup> Yau et al. Global Prevalence and Major Risk Factors of Diabetic Retinopathy, Diabetes Care 2012 Mar; 35(3): 556-564.  
<sup>(3)</sup> <https://preventionofblindness.org/diabetic-macular-edema-dme/>  
<sup>(4)</sup> DRG Diabetic Macular Edema / Diabetic Retinopathy Disease Landscape & Forecast 2020  
<sup>(5)</sup> Berenberg and Kiss: "Real-World Utilization of Anti-VEGF Agents", Review of Ophthalmology, Feb 5, 2016

# OCS-01 | Current DME Treatment Paradigm Leaves Two Patient Segments Undertreated and Losing Vision



**Addressable US patient population: 1.2 million<sup>(4)(6)</sup>**

(1) Optical coherence tomography (OCT) imaging.

(2) Baseline Demographics and Clinical Characteristics of Treatment-Naive Patients with Diabetic Macular Edema Listed in the IRIS Registry (Table S3) www.aao.org

(3) Baker, Carl W., et al. "Effect of initial management with aflibercept vs laser photocoagulation vs observation on vision loss among patients with diabetic macular edema involving the center of the macula and good visual acuity: a randomized clinical trial." *Jama* 323.19 (2019): 1880-1894.

(4) Gonzalez: 2016 Early and Long-term Responses to VEGF Therapy in DME: Analysis of protocol I data

(5) Kiss 2014; Berenger and Kiss, Feb. 2016, Real-world Utilization of VEGF agents (DME section), *Review of Ophthalmology* <https://www.reviewofophthalmology.com/article/realworld-utilization-of-antivegf-agents>

(6) Decision Resources Group: DME - DR Landscape Forecast - Disease Landscape Forecast 2020

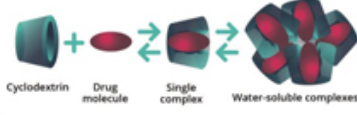
# OCS-01 | First Eye Drop for DME – Results Consistent with Previous Trials

## OCS-01 shown to be superior to vehicle on BCVA and CST endpoints in Phase 2 trial

Unique product candidate with clinically validated MOA

OCS-01: High-concentration Optireach® formulation of dexamethasone (15mg/ml)

**OPTIREACH®**  
Formulation Technology



Ozurdex®, an IVT implant of dexamethasone, is FDA-approved for DME and annualizing at \$460M and 7% growth<sup>1</sup>

Positive results in exploratory and Phase 2 studies in DME

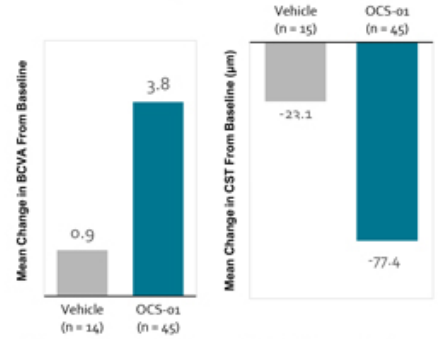
**DME Exploratory 1<sup>2</sup>**  
19 pts Tanito Study  
successfully completed

**DME Exploratory 2<sup>3</sup>**  
22 pts Ohira Study  
successfully completed

**DME Phase 2<sup>4</sup> 144 pts**  
Randomized & double-masked  
successfully completed

Positive Phase 2 results<sup>5</sup>

**Change in BCVA & CST**  
(Same Patient Population as Ph3 Diamond Trial)



Phase 2 results supported successful End of Phase 2 Meeting

1. Abbvie Q1 2023 earnings report  
 2. Investigator-initiated, open-label, single-center study. Tanito M, et al. Invest Ophthalmol Vis Sci. 2015;52:7944-7948  
 3. Ohira A, et al. Acta Ophthalmologica. 2015;93:610-615. Ohira A, et al. Acta Ophthalmologica. 2015;93:610-615.  
 4. DME Phase 2. Note: Data presented at Angiogenesis, Exudation and Degeneration, 2020 by KOL (Dugel P)  
 5. Dugel P. The Oculis OCS-01 phase 2 study: an effective topical therapeutic for DME. Presented at: Angiogenesis, Exudation, and Degeneration 2020; Feb. 8, 2020; Miami  
 Central macular thickness (CMT), Best-corrected visual acuity (BCVA)  
 visual acuity (BCVA); Dugel PU. The Oculis OCS-01 phase 2 study: an effective topical therapeutic for DME. Presented at: Angiogenesis, Exudation, and Degeneration 2020; Feb. 8, 2020; Miami.

---

# Diamond

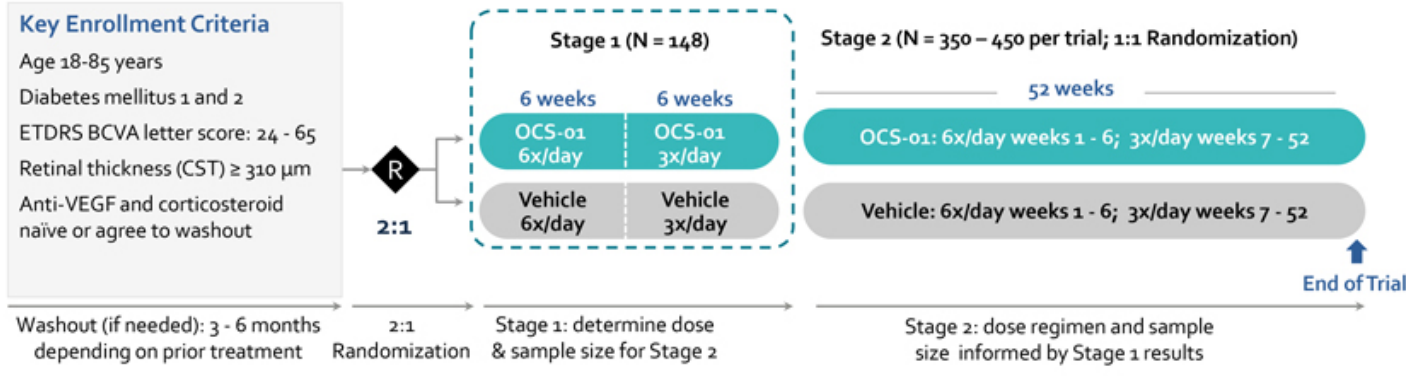
DIAbetic Macular edema patients ON a Drop

## Stage 1 Trial Results



# OCS-01 | Phase 3 Program in DME Patients

Loading dose regimen & enriched population increase probability of success



**Stage 1: Assess if loading dose optimizes efficacy**

- 1<sup>o</sup> endpoint:** Change in BCVA ETDRS letter score at wk 6
- 2<sup>o</sup> endpoint:** % with a  $\geq 3$ -line (15 letters) gain in BCVA at wk 6
- 2<sup>o</sup> endpoint:** Change in CST as measured by SD-OCT<sup>(1)</sup> at wk 6
- 2<sup>o</sup> endpoint:** Change in BCVA at wk 12

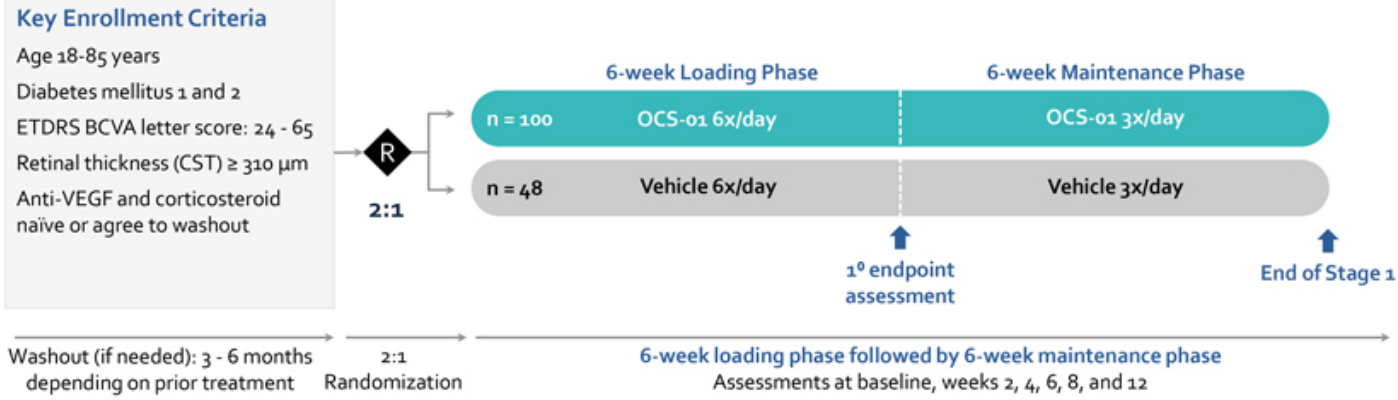
**Stage 2: Two Phase 3's to support NDA filing for DME**

- 1<sup>o</sup> endpoint:** BCVA at wk 52
- Key 2<sup>o</sup> endpoint:**  $\geq 3$ -line (15 letters) at wk 52
- 2<sup>o</sup> endpoint:** CST at wk 52

(1) Spectral Domain Optical Coherence Tomography

# OCS-01 | Phase 3 in DME Patients – Stage 1

Loading dose regimen & enriched population increase probability of success



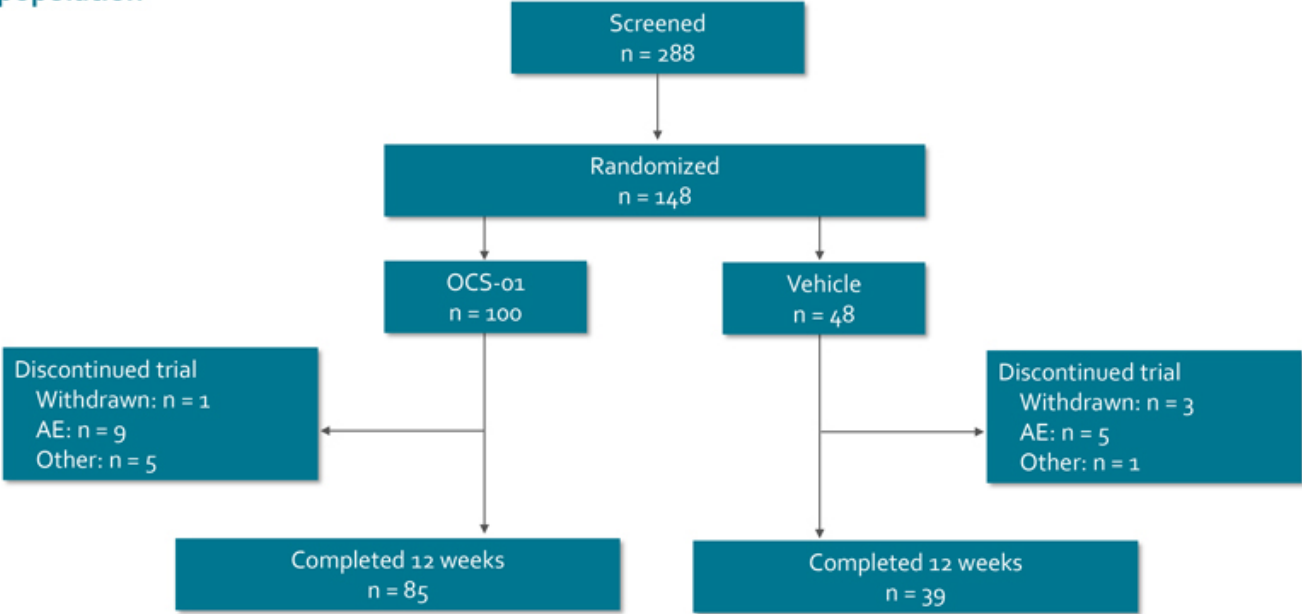
**Stage 1 : Assess if loading dose optimizes efficacy**

- 1<sup>o</sup> endpoint: Change in BCVA ETDRS letter score at wk 6
- 2<sup>o</sup> endpoint: % with a  $\geq 3$ -line (15 letters) gain in BCVA at wk 6/12
- 2<sup>o</sup> endpoint: Change in CST as measured by SD-OCT<sup>(1)</sup> at wk 6/12
- 2<sup>o</sup> endpoint: Change in BCVA at wk 12

(1) Spectral Domain Optical Coherence Tomography

# Patient Disposition

## ITT population



AE, adverse event; ITT, intention-to-treat.  
Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

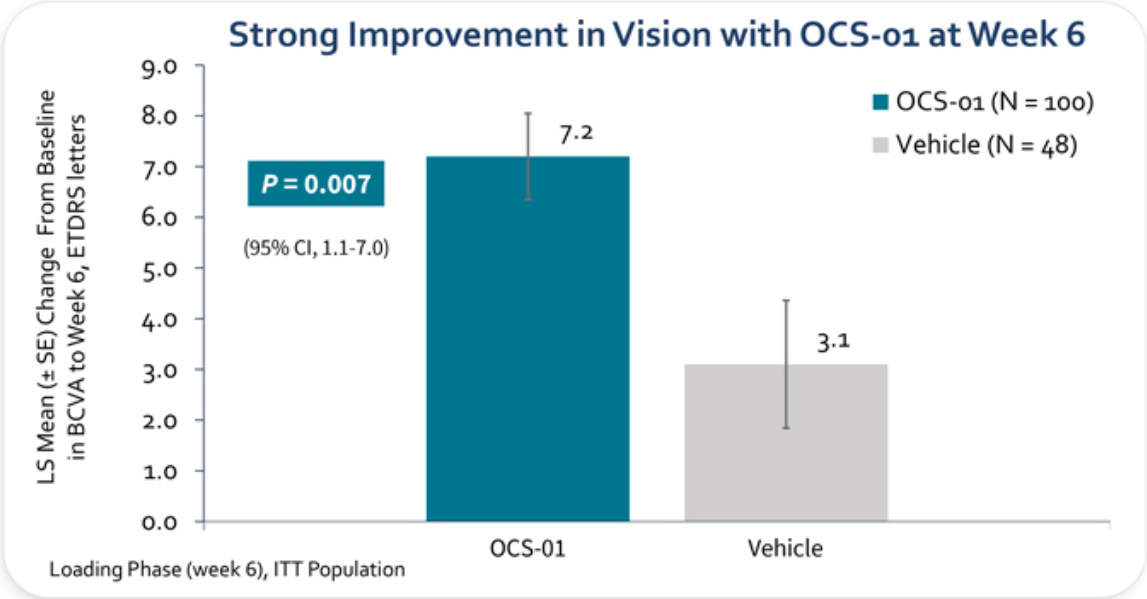
## Demographics: Well-balanced Between Arms

| Parameter                            | OCS-01 (n = 100) | Vehicle (n = 48) |
|--------------------------------------|------------------|------------------|
| Age, mean (SD), years                | 61.9 (9.0)       | 63.9 (7.3)       |
| Male, n (%)                          | 53 (53.0)        | 26 (54.2)        |
| Duration of DME, mean (SD), years    | 2.0 (2.6)        | 1.9 (2.7)        |
| BCVA, mean (SD), ETDRS letter score  | 57.5 (9.3)       | 58.3 (7.5)       |
| CST, mean (SD), $\mu\text{m}$        | 453.0 (131.8)    | 445.3 (112.5)    |
| IOP <sup>(1)</sup> , mean (SD), mmHg | 15.3 (3.1)       | 14.7 (3.0)       |

<sup>(1)</sup> Intraocular pressure. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

# Primary Endpoint Achieved with Robust Statistical Significance

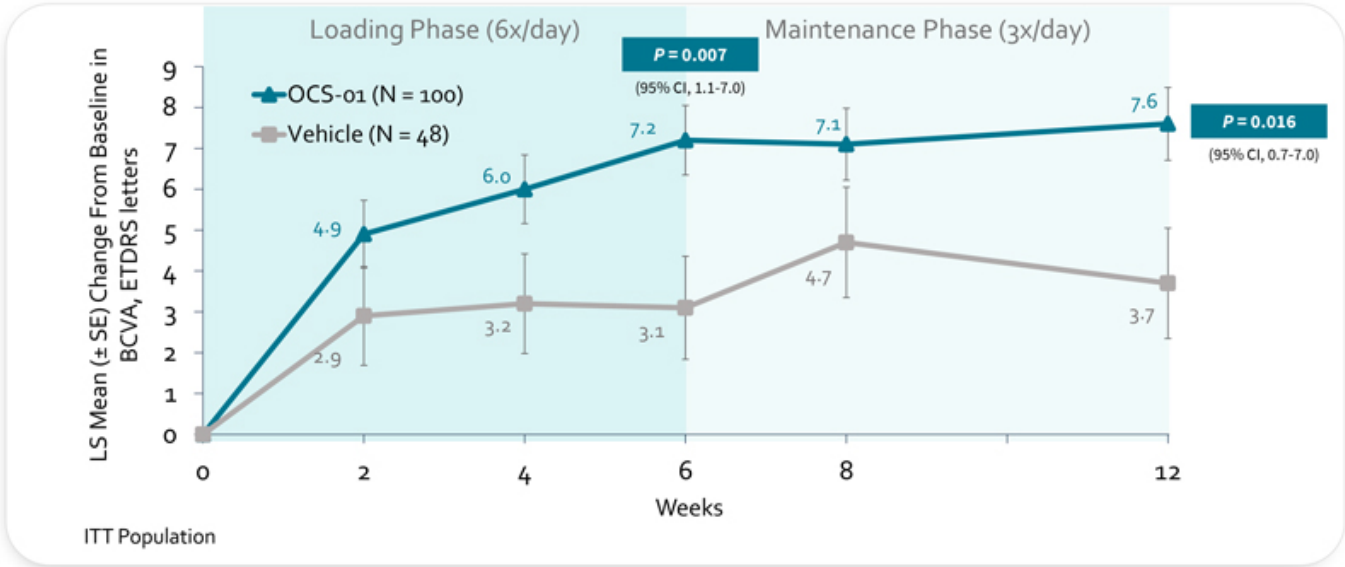
Rapid improvement in vision with OCS-01 treatment, as assessed by BCVA



BCVA, best corrected visual acuity; CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; ITT, intention-to-treat; LS, least squares; SE, standard error. Multiple imputations for missing data. Imputation rules are applied based on a pattern-mixed model approach. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

# Improvement in Vision with OCS-01 Sustained to Week 12

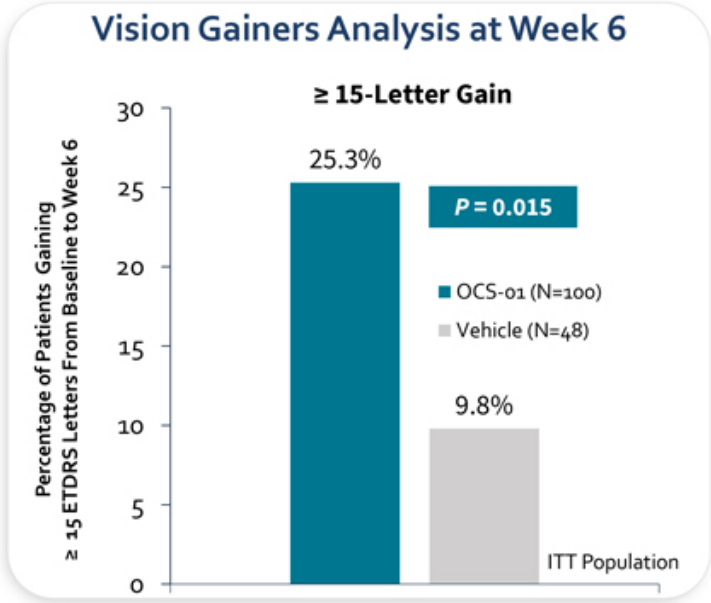
Rapid improvement in BCVA with loading dose regimen sustained with maintenance regimen



BCVA, best corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; ITT, intention-to-treat; SD, standard deviation; SE, standard error. Multiple imputations for missing data. Imputation rules are applied based on a pattern-mixed model approach. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

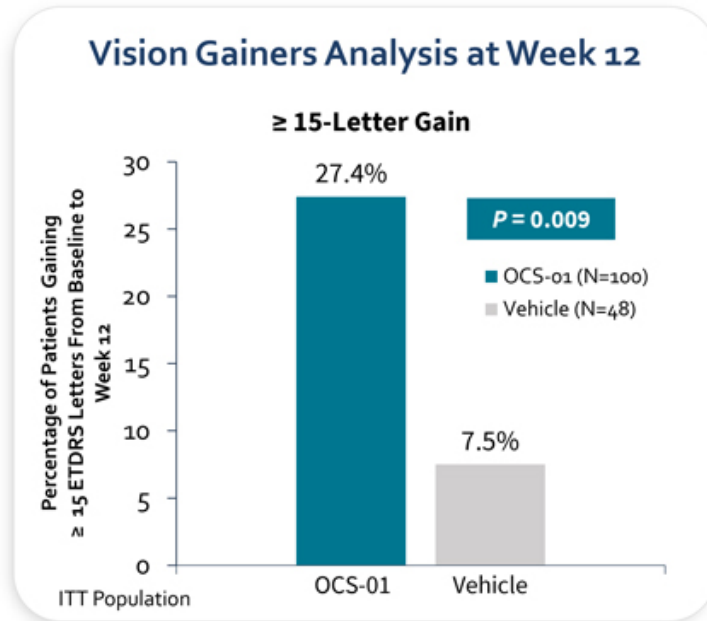
# 25% of OCS-01 Patients Achieve $\geq 3$ Line Improvement in BCVA at Week 6

3-line (15 letter) improvement in BCVA deemed highly clinically relevant



ETDRS, Early Treatment Diabetic Retinopathy Study; ITT, intention-to-treat. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

27% of OCS-01 Patients with  $\geq 3$ -Line Improvement in BCVA at Week 12  
3-line (15 letter) improvement in BCVA deemed highly clinically relevant

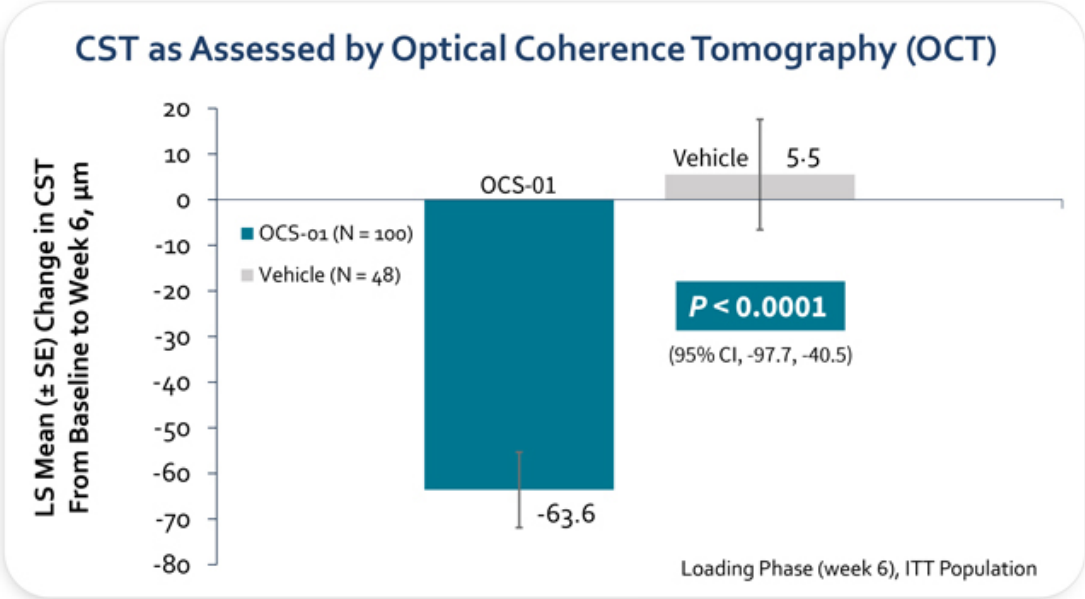


ETDRS, Early Treatment Diabetic Retinopathy Study; ITT, intention-to-treat.  
Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.



# 63.6 $\mu\text{m}$ Reduction in CST Achieved with OCS-01 at Week 6

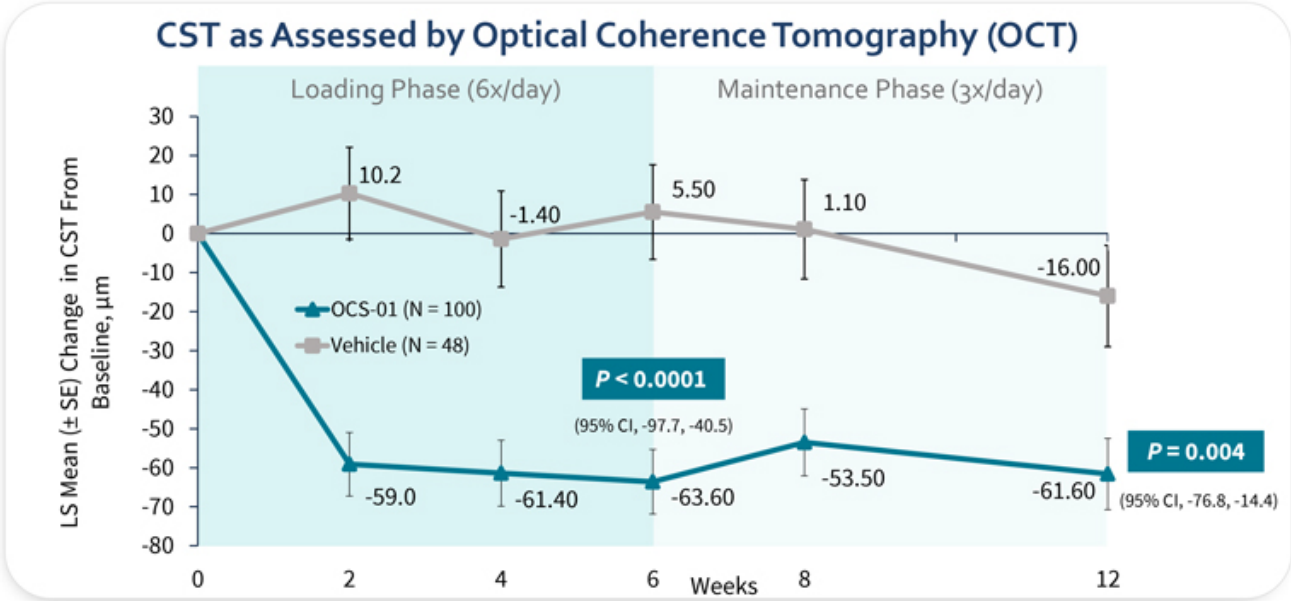
Central subfield thickness (CST) is a key metric used by physicians to manage DME patients



CI, confidence interval; CST, central subfield thickness; ITT, intention-to-treat; LS, least squares; SE, standard error. Multiple imputations for missing data. Imputation rules are applied based on a pattern-mixed model approach. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

# Reduction in CST Achieved with OCS-01 Sustained to Week 12

Rapid improvements in CST with loading dose regimen sustained with maintenance regimen



BCVA, best corrected visual acuity; CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; ITT, intention-to-treat; LS, least squares; SE, standard error. imputations for missing data. Imputation rules are applied based on a pattern-mixed model approach. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

# No Unexpected Safety Findings

## Treatment Emergent Adverse Events

|                                | OCS-01 (N = 100)<br>n (%) | Vehicle (N = 48)<br>n (%) |
|--------------------------------|---------------------------|---------------------------|
| Any TEAE                       | 70 (70.0)                 | 30 (62.5)                 |
| Diabetic retinal edema         | 10 (10.0)                 | 9 (18.8)                  |
| Intraocular pressure increased | 14 (14.0)                 | 1 (2.1)                   |
| Hypertension                   | 10 (10.0)                 | 1 (2.1)                   |
| Ocular hypertension            | 8 (8.0)                   | 0                         |
| Macular edema                  | 2 (2.0)                   | 4 (8.3)                   |
| COVID-19                       | 2 (2.0)                   | 2 (4.2)                   |
| Dry eye                        | 3 (3.0)                   | 1 (2.1)                   |
| Diabetes mellitus              | 3 (3.0)                   | 0                         |
| Dizziness                      | 3 (3.0)                   | 0                         |
| Dysgeusia                      | 3 (3.0)                   | 0                         |
| Nasopharyngitis                | 2 (2.0)                   | 1 (2.1)                   |
| Type 2 diabetes                | 2 (2.0)                   | 1 (2.1)                   |
| Visual acuity reduced          | 1 (1.0)                   | 2 (4.2)                   |
| Vitreous haemorrhage           | 2 (2.0)                   | 1 (2.1)                   |
| Arthralgia                     | 2 (2.0)                   | 0                         |
| Blood glucose increased        | 2 (2.0)                   | 0                         |

TEAE, treatment-emergent adverse event.

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

## Treatment Emergent Serious Adverse Events (SAE)

|                      | OCS-01 (N = 100)<br>n (%) | Vehicle (N = 48)<br>n (%) |
|----------------------|---------------------------|---------------------------|
| Any ocular SAE       | 1 (1.0)                   | 0                         |
| Vitreous haemorrhage | 1 (1.0)                   | 0                         |
| Any non-ocular SAE   | 4 (4.0)                   | 3 (6.3)                   |
| Death                | 1 (1.0)                   | 0                         |

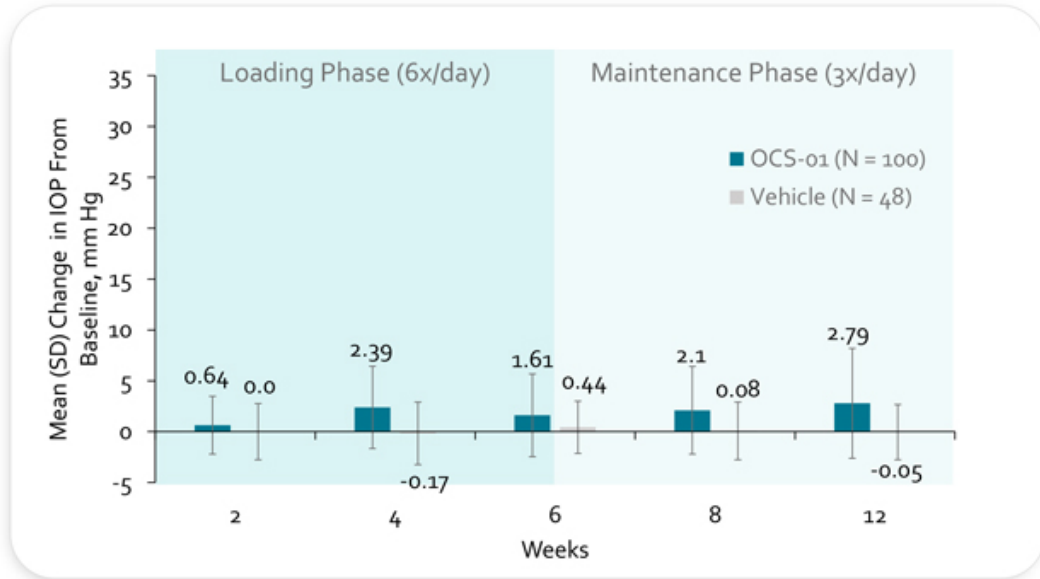
- None of the SAEs reported were deemed related to study drug
- No evidence of cataract formation up to 12 weeks

## IOP Increase Consistent with Literature

|   | OCS-01<br>n=100<br>n (%) | Vehicle<br>n=48<br>n (%) |
|---|--------------------------|--------------------------|
| Any IOP related AE                            | 22/100 (22.0)            | 1/48 (2.1)               |
| 10 mmHg IOP change from baseline at any visit | 16/97 (16.5)             | 0/47 (0)                 |
| Higher than 25 mmHg IOP at any visit          | 19/97 (19.6)             | 1/47 (2.1)               |
| Higher than 35 mmHg IOP at any visit          | 1/97 (1.0)               | 0/47 (0)                 |
| IOP lowering medications administered for AE  | 11/22                    | 1/1                      |

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

# Minimal Mean IOP Increase is Similar Across Loading and Maintenance



IOP, intraocular pressure. Mean (SD) baseline IOP: OCS-01, 15.3 (3.1) mm Hg; vehicle, 14.7 (3.0) mm Hg. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

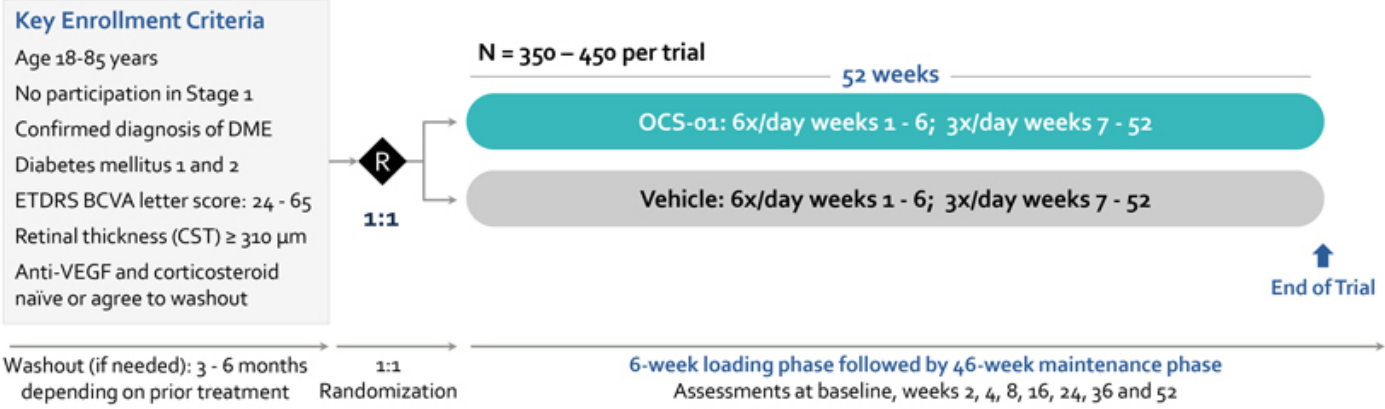
|   | OCS-01<br>(n = 100) | Vehicle<br>(n = 48) | Vehicle Adjusted<br>Change | P Value  |
|---|---------------------|---------------------|----------------------------|----------|
| Mean Change in BCVA at Week 6           | +7.2 letters        | +3.1 letters        | +4.1 letters               | 0.007    |
| Mean Change in BCVA at Week 12          | +7.6 letters        | +3.7 letters        | +3.9 letters               | 0.016    |
| % with ≥ 3-line gain in BCVA at Week 6  | 25.3%               | 9.8%                | 15.5%                      | 0.015    |
| % with ≥ 3-line gain in BCVA at Week 12 | 27.4%               | 7.5%                | 19.9%                      | 0.009    |
| Mean Change in CST at Week 6            | -63.6 μm            | +5.5 μm             | -69.1 μm                   | < 0.0001 |
| Mean Change in CST at Week 12           | -61.6 μm            | -16.0 μm            | -45.6 μm                   | 0.004    |

No unexpected safety findings observed

**Next Step: Continuation of Ph 3 program to support NDA filing for treatment of DME**

# OCS-01 | Next Step: Phase 3 DME Trial Stage 2

Two global Ph 3 trials (N = 350-450 each) to support NDA filing for treatment of DME



**Endpoints**

- 1<sup>o</sup> endpoint:** Change in BCVA ETDRS letter score at wk 52
- Key 2<sup>o</sup> endpoint:** % with  $\geq 3$ -line gain in BCVA at wk 52
- 2<sup>o</sup> endpoint:** Change in CST as measured by SD-OCT<sup>(1)</sup> at wk 52

**Anticipated Timelines**

**Stage 2 Start:** 2H 2023

(1) Spectral Domain Optical Coherence Tomography



# Summary



## OCS-01 Ph 3 Stage 1 Recap

- **Trial objectives met:** Results validated loading and maintenance regimen to optimize OCS-01 efficacy potential in DME with **robust statistical significance**
- OCS-01 met **all Functional and Clinical benefit endpoints** in a robust, statistically superior manner (in 3-month trial):
  - Improvement of visual acuity (**Functional Endpoint**)
  - Increase in proportion of patients with a 3-line or greater gain (**Clinical Benefit Endpoint**)
  - Reduction in macular edema as measured by OCT imaging (**Pharmacodynamic Endpoint**)
- No unexpected safety findings observed

**Next Step: Commence Stage 2 of Ph 3 program to support NDA filing of OCS-01 for DME treatment**

# Innovative, Diversified and Late-stage Pipeline



| Product Candidate(s)               | Investigational Indication(s)                                   | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Next Catalysts                    |              |
|------------------------------------|---|--------------|---------|---------|---------|-----------------------------------|--------------|
|                                    |   |              |         |         |         | 2023                              | 2024         |
| OCS-01<br>Optireach®<br>technology | DIABETIC MACULAR EDEMA  |              |         |         |         | 1 <sup>o</sup> endpt. met Stage 1 |              |
|                                    | INFLAMMATION AND PAIN FOLLOWING OCULAR SURGERY                  |              |         |         |         | Ph3 readout                       | NDA          |
|                                    | CYSTOID MACULAR EDEMA   |              |         |         |         |                                   | PoC readout  |
| OCS-02<br>Anti TNF                 | DRY EYE DISEASE   |              |         |         |         |                                   | Ph2b readout |
|                                    | UVEITIS   |              |         |         |         |                                   | Ph2b readout |
| OCS-05<br>SGK2<br>Activator        | ACUTE OPTIC NEURITIS  |              |         |         |         |                                   | PoC readout  |
|                                    | GLAUCOMA  |              |         |         |         |                                   |              |
|                                    | GEOGRAPHIC ATROPHY  |              |         |         |         |                                   |              |
|                                    | DIABETIC RETINOPATHY  |              |         |         |         |                                   |              |
|                                    | NEUROTROPHIC KERATITIS  |              |         |         |         |                                   |              |
| OCS-03                             | CORNEAL NV, PTERYGIUM   |              |         |         |         |                                   |              |
| OCS-04                             | CORNEAL TRANSPLANT  |              |         |         |         |                                   |              |
| (Undisclosed)                      | Wet-AMD <sup>(1)</sup> , RVO <sup>(2)</sup> , DR <sup>(3)</sup> |              |         |         |         |                                   |              |

OCS-01 is based on the OPTIREACH® technology, OCS-02 is a single chain antibody fragment (ScFv) against TNF $\alpha$  and OCS-05 is a SGK-2 activator peptidomimetic small molecule with novel MoA targeting the activation of the trophic factor pathways.

(1) Age-related macular degeneration (AMD).

(2) Retinal Vein Occlusion (RVO).

(3) Diabetic Retinopathy (DR).

Targeting critical unmet needs in 3 major ophthalmology segments

- **OCS-01: 1<sup>st</sup> Eye drop for Diabetic Macular Edema (DME) in Ph3**
- **OCS-02: 1<sup>st</sup> Biologic eye drop for Dry Eye Disease (DED) in Ph2b**  
*(upside potential from biomarker-driven precision medicine approach)*
- **OCS-05: 1<sup>st</sup> Neuroprotective agent for neuro-retina treatments in PoC**

Near-term value inflection points expected

2023

2024

- ✓ **OCS-01 DME Phase 3 (Stage 1) readout**
- **OCS-01 Ocular Surgery Phase 3 readout**
- **OCS-01 Ocular Surgery NDA**
- **OCS-01 CME<sup>(1)</sup> PoC readout**
- **OCS-02 DED Phase 2b readout**
- **OCS-02 Uveitis Phase 2b readout**
- **OCS-05 AON<sup>(2)</sup> PoC readout**

(1) Cystoid Macular Edema (CME).  
(2) Acute Optic Neuritis (AON).



## Our Purpose

To drive innovation to save sight and improve eye care

## Q&A Session

Moderated by:

Dr. Pravin Dugel

Director, Oculis Holding AG

