Oculis Announces Completion of Last Patient Visit in Phase 3 DIAMOND Program with OCS-01 Eye Drops for the Treatment of Diabetic Macular Edema

Apr 20, 2026

- *Last patient visits for both OCS-01 Phase 3 DIAMOND trials (total 800+ patients) are complete, with topline results expected in June 2026*
- *A non-invasive topical treatment for diabetic macular edema (DME) has the potential to address significant unmet needs for early treatment intervention and for inadequate responders to the current standard of care*[2-4]
- *OCS-01 aims to transform the treatment paradigm as the first topical treatment for DME, a leading cause of vision loss in the working-age population in most developed countries*[1]

ZUG, Switzerland, April 20, 2026 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) (Oculis), a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in ophthalmology and neuro-ophthalmology, today announced completion of the final patient visit in the OCS-01 Phase 3 DIAMOND program in diabetic macular edema (DME). Oculis expects to report topline results in June 2026.

Riad Sherif, M.D., Chief Executive Officer of Oculis, stated, "The completion of the last patient visit in both DIAMOND Phase 3 trials represents a pivotal milestone as we advance towards anticipated topline results in June. This achievement reflects our commitment to advancing OCS-01 as a potential first-in-class eye drop therapy for DME, a leading cause of blindness in working-age adults. With multiple catalysts on the horizon across our late-stage portfolio, including the ongoing PIONEER registrational program evaluating Privosegtor in optic neuropathies and PREDICT-1, the first genotype-based registrational trial to drive precision medicine in dry eye disease, with Licaminlimab, Oculis continues to execute on its mission to deliver transformative innovations that address critical unmet needs in ophthalmology and neuro-ophthalmology."

Arshad M. Khanani, M.D., M.A., FASRS, DIAMOND Program Steering Committee Chairperson, Oculis Board of Directors member, Scientific Advisory Board Chair of Retina and Director of Clinical Research at Sierra Eye Associates, added, "DME continues to pose a major challenge in clinical practice, with many patients inadequately served by current therapies due to high treatment burden and sub-optimal response. A non-invasive topical option like OCS-01 could significantly reshape how DME is managed. This is especially important for patients with mild vision loss who are typically observed without active treatment, as well as for those who respond poorly to existing therapies or struggle with the burden of frequent injections. I am eagerly awaiting the topline results from the Phase 3 DIAMOND program later this quarter."

The last patient in the DIAMOND (DIAbetic Macular edema patients ON a Drop) program, consisting of two Phase 3, double-masked, randomized, multi-center trials to evaluate the efficacy and safety of OCS-01 eye drops in patients with DME following 52 weeks of treatment, completed the final study visit in April 2026. Both registrational 52-week trials were initiated upon the positive findings from Stage 1 of the DIAMOND program, in which patients treated with OCS-01 experienced significant improvements in visual acuity and a rapid reduction of edema. Oculis expects to report topline data from both pivotal trials in June, followed by a potential NDA submission in Q4 2026.

Despite available invasive therapies, an estimated 1 million patients out of the 1.8 million people diagnosed with DME in the U.S. remain untreated or underserved.[2-4] Significant unmet medical needs remain for early treatment intervention and inadequate responders to the standard of care (SOC). An analysis of real-world evidence from the IRIS Registry showed that approximately 60% of newly diagnosed DME patients remained untreated one year after diagnosis.[5] Furthermore, according to the DRCR Retina Network Protocol I, an estimated 40% of treated DME patients have an inadequate response to the current SOC.[4] This suboptimal response reflects DME's multifactorial pathophysiology, which also involves inflammatory pathways, underscoring the need for alternative therapeutic approaches. OCS-01 is intended to be strategically positioned to capture this significant opportunity by providing a non-invasive, topical eye drop for those requiring early intervention and a versatile option for patients who do not respond to existing injections, thereby potentially expanding the current market estimated at $3 billion in the U.S. alone.[2]

About OCS-01 eye drops and the OPTIREACH® technology
Leveraging Oculis' proprietary technology, OCS-01 is an OPTIREACH® formulation of high concentration dexamethasone eye drop. It is being developed as an eye drop to treat the retina to offer a non-invasive treatment alternative for diabetic macular edema (DME). This route of administration enables easy access to treatment in the early stages of the disease and can be used in combination with other therapies in later stages. In contrast, all currently available treatments require invasive delivery methods, such as intravitreal injections or ocular implants, to reach 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. Oculis' OCS-01 is being developed with the aim to transform the current treatment paradigm in DME as a non-invasive topical treatment option.

OCS-01 is an investigational drug in Phase 3 development that has not received regulatory approval for commercial use in any country.

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[1,2]. DME is an irreversible and progressive complication of diabetic retinopathy and is related to consistently having 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 safe, efficacious, and less burdensome treatments for DME patients.

About the Phase 3 DIAMOND Program of OCS-01 in Diabetic Macular Edema

The DIAMOND-1 (DIAbetic Macular edema patients ON a Drop) and DIAMOND-2 trials are Phase 3, double-masked, randomized, multi-center trials which are evaluating the efficacy and safety of OCS-01 eye drops in patients with DME. Oculis enrolled over 800 patients across both pivotal trials who were randomized 1:1 to receive OCS-01 or vehicle six times daily for the 6-week induction phase and then three times daily through week 52 for the maintenance phase. The primary endpoint is change in best corrected visual acuity early treatment diabetic retinopathy study (BCVA ETDRS) letter score at Week 52 compared with baseline. Secondary endpoints include percentage of patients with ≥15-letter gain in BCVA and change in central

subfield thickness (CST), both at Week 52 compared with baseline. Both trials were initiated upon the positive findings from Stage 1 of the DIAMOND program, which was announced in the second quarter of 2023.

About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology. Oculis' highly differentiated late-stage clinical pipeline includes three core product candidates: Privosegtor, a breakthrough neuroprotective candidate in the PIONEER program which consists of studies intended to support registration plans for treatment in optic neuropathies like optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION), with potentially broad clinical applications in various other neuro-ophthalmic and neurological diseases; OCS-01, an eye drop in pivotal registration studies, aiming to become the first non-invasive topical treatment for diabetic macular edema (DME); and Licaminlimab, a novel, topical anti-TNFα in registrational trial, which is being developed with a genotype-based approach to drive precision medicine in dry eye disease (DED). Headquartered in Switzerland with operations in the U.S. and Iceland, Oculis is led by an experienced management team with a successful track record and supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

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Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the potential benefits of the Company's product candidates, including the potential of OCS-01 to become the first topical treatment for DME, the initiation, timing, progress and results of current and future clinical trials, Oculis' research and development programs, regulatory and business strategy; Oculis' future development plans; the timing or likelihood of regulatory filings and approvals; and statements about market opportunity, 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. 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' annual report on Form 20-F and any other documents filed with the SEC. Copies of these documents are available on the SEC's website, 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.

References:

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