Oculis Completes Enrollment in both DIAMOND Phase 3 Trials of OCS-01 in Diabetic Macular Edema

Apr 10, 2025

ZUG, Switzerland, April 10, 2025 (GLOBE NEWSWIRE) --

- *DIAMOND is the first and only pivotal trial program ever conducted with a topical treatment for diabetic macular edema (DME)*
- *Over 800 patients randomized in DIAMOND-1 or DIAMOND-2 Phase 3 trials at an industry-leading record speed across 119 sites worldwide primarily in the US; topline data readout expected in Q2 2026 with NDA submission to follow*
- *Company to provide an update on the DIAMOND program and its innovative late-stage pipeline at the upcoming in-person and virtual R&D Day on Tuesday, April 15*

Oculis Holding AG (Nasdaq: OCS / ICX: OCS.IC) ("Oculis"), a global biopharmaceutical company focused on innovations addressing ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs, today announced that it has completed enrollment in both Phase 3 DIAMOND-1 and DIAMOND-2 trials of OCS-01 eye drops in DME, designed as pivotal registration studies to support global marketing applications including NDA submission and approval by the U.S. Food and Drug Administration (FDA). The trials enrolled over 800 patients at 119 investigative sites throughout the United States and several other countries.

Rapid completion of enrollment in the DIAMOND (DIAbetic Macular edema patients ON a Drop) program, consisting of two (2) 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, is an important milestone. Topline data from both Phase 3 trials is expected in the second quarter of 2026, with NDA submission to follow thereafter.

If approved, OCS-01 is expected to become the first topical eye drop for the treatment of DME and address unmet medical needs for early treatment intervention or for patients with inadequate response to anti-VEGF therapy.

Riad Sherif, M.D., Chief Executive Officer of Oculis, said: "The completion of enrollment in both the DIAMOND-1 and DIAMOND-2 Phase 3 trials shows strong focus on disciplined execution. I would like to thank all stakeholders participating in the trials and the whole medical community for their excellent support to advance this program towards NDA submission, which keeps us on track for a topline data readout from both studies in the second quarter of 2026. For the months to come, we will remain focused on execution to ensure the program's continued advancement, bringing us closer to potentially providing a transformational solution, with the first non-invasive topical eye drop therapy, for patients suffering from DME."

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, commented: "Together with my colleagues on the DIAMOND steering committee, I am greatly encouraged by the ongoing strong progress of OCS-01 and the Phase 3 program. It's exciting to witness the enthusiasm from the investigators due to the positive results seen in Stage 1 of the DIAMOND program. The rapid enrollment of over 800 patients in both trials not only reflects the recognition among investigators of OCS-01's significant potential as an effective, non-invasive therapy for DME, but also demonstrates the high level of patient interest in a topical eye drop treatment."

An update on the progress of the Phase 3 DIAMOND-1 and DIAMOND-2 trials will be included in Oculis' upcoming in-person and virtual R&D Day on Tuesday April 15. Register for the event here.

To learn more about the Phase 3 DIAMOND trials, please visit diamondtrial.com.

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About OCS-01 eye drops and 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 could 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 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 will evaluate the efficacy and safety of OCS-01 eye drops in patients with DME. Oculis has enrolled over 800 patients across both pivotal trials who have been 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. Secondary endpoints include percentage of patients with ≥15-letter gain in BCVA and change in central subfield thickness (CST), both at Week 52. 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) purposefully driven to save sight and improve eye care. Oculis' highly differentiated pipeline of multiple innovative product candidates in clinical development includes: OCS-01, a topical eye drop candidate for diabetic macular edema (DME); Privosegtor (OCS-05), a neuroprotective candidate for acute optic neuritis with potentially broad clinical applications in other neuro-ophthalmic diseases; and Licaminlimab (OCS-02), a topical biologic anti-TNFα eye drop candidate for 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 is 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 OCS-01, including patient impact and market opportunity; the potential of OCS-01 to become the first non-invasive topical eye drop therapy for DME; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical trials, including the progress of Oculis' DIAMOND Phase 3 trials of OCS-01 eye drops in DME and the topline data readout from both Phase 3 trials expected in the second quarter of 2026; 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. 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 U.S. Securities and Exchange Commission (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.

(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 Estimated diabetes prevalence worldwide in 2021: 537m, reaching 783m in 2045