Oculis Announces Topline Results from DIAMOND Phase 3 Trials with OCS-01 in Diabetic Macular Edema

May 29, 2026

- *The primary endpoint of mean change in best corrected visual acuity (BCVA) from baseline to week 52 in both Phase 3 trials was not met*
- *The secondary endpoint of retinal thickness showed a substantial and persistent reduction with OCS-01 vs vehicle in both trials*
- *Oculis will focus its developmental efforts and financial resources on the ongoing Privosegtor PIONEER registrational program in optic neuropathies and the Licaminlimab PREDICT-1 registrational trial in dry eye disease*
- *Financial position remains strong with $278 million in cash, cash equivalents, and short-term investments as of March 31, 2026, providing cash runway into 2H 2029*

Conference call today at 4:30 pm ET

ZUG, Switzerland, May 29, 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 neuro-ophthalmology and ophthalmology, today announced topline results from its Phase 3 DIAMOND-1 and DIAMOND-2 trials of OCS-01 eye drops in patients with diabetic macular edema (DME).

The DIAMOND (DIAbetic Macular edema patients ON a Drop) program consisted 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. Over 800 patients were enrolled across both pivotal trials at 119 investigational sites throughout the United States and several other countries.

The primary endpoint, mean change in best corrected visual acuity early treatment diabetic retinopathy study (BCVA ETDRS) letter score at Week 52, was not met in both trials. The secondary endpoint of retinal thickness, as measured by OCT, showed a substantial and persistent reduction with OCS-01 vs vehicle at all visits in DIAMOND-2 and at all visits except Week 52 in DIAMOND-1. The key secondary endpoint of the proportion of patients with ≥15-letter gain in BCVA was not met in both trials.

OCS-01 was well tolerated, with no unexpected adverse events observed, and the overall safety profile was consistent with that of previous trials.

Based on the results, at this time, Oculis does not plan to pursue an FDA regulatory filing for OCS-01 in DME.

Riad Sherif, M.D., Chief Executive Officer of Oculis, said: “We are naturally disappointed that the substantial and sustained reduction in retinal thickness observed across both trials didn’t translate into BCVA improvement at week 52. In these two trials, our team partnered with 119 global sites across multiple countries and demonstrated excellent execution. We thank the patients, investigators, and all clinical experts who participated in the DIAMOND program. Our strong financial position allows us to execute on our robust late-stage development portfolio. While we finalize the review of DIAMOND program data, we will strategically focus resources on advancing our late-stage portfolio, including the Privosegtor platform, starting with the PIONEER program for Privosegtor in optic neuropathies, and the PREDICT-1 trial for Licaminlimab to drive precision medicine in dry eye disease.”

Analyst and investor call
The Oculis management team will host an analyst and investor call today at 4:30 pm U.S. Eastern Time, to review the topline results and provide a pipeline update. Interested parties may participate in the call via the following webcast link:
https://viavid.webcasts.com/starthere.jsp?ei=1765661&tp_key=0d6c454cfe

Or use the following dial-in options:
US-based Investors: 1-877-407-4018
International Investors: 1-201-689-8471
Conference ID: 13760937

A replay of the webcast 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.

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 focuses on two core product candidates. Privosegtor is a breakthrough neuroprotective candidate in the PIONEER program, which consists of studies intended to support registration plans for treatment of optic neuropathies, including optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION). Privosegtor also has potential to be developed for additional indications in other neuro-ophthalmic and neurological diseases. Licaminlimab is a novel, topical anti-TNFα in a registrational trial, and is being developed with a genotype-based approach for treating patients with dry eye disease (DED). Headquartered in Switzerland with operations in the U.S., Iceland and Switzerland, 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, 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 Oculis' cash runway are forward-looking. The clinical trial results presented in this press release are topline and preliminary and subject to change, as analysis is ongoing. 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.