Oculis to Present Clinical Trial Results in Diabetic Macular Edema and Acute Optic Neuritis at Ophthalmology Conferences

Sep 1, 2025

Phase 2 ACUITY trial results for Privosegtor (OCS-05) in acute optic neuritis to be presented in EURETINA late-breaking session

Expanded data analysis from Phase 3 Stage 1 DIAMOND program for OCS-01 eye drops in diabetic macular edema (DME) to be presented

ZUG, Switzerland, Sept. 01, 2025 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) ("Oculis"), a global biopharmaceutical company focused on innovations for ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs, today announced upcoming presentations at the Ophthalmology Futures Retina Forum, the EURETINA Innovation Spotlight (EIS), the 25th European Society of Retina Specialists (EURETINA) Congress, and the Retina Society Annual Congress.

Oculis will present clinical trial results from its innovative late-stage pipeline, including expanded data analyses from Stage 1 of the Phase 3 DIAMOND program on subgroups by lens status and prior treatment status. The results highlight the potential of OCS-01 to benefit various DME patient profiles, including phakic and pseudophakic patients, as well as treatment naïve and previously treated patients.

Data from the Phase 2 ACUITY trial investigating Privosegtor (OCS-05), a potential neuroprotective therapy for acute optic neuritis, will be presented during the late-breaking session at the 25th EURETINA Congress. Previously disclosed headline results from the trial showed clinically meaningful visual function improvement with anatomical neuroprotection benefits in patients treated with Privosegtor, suggesting potential applicability in multiple retinal, neuro-ophthalmological and neurological conditions.

Additionally, the winner of the annual Ramin Tadayoni Award will be announced during the EURETINA opening ceremony on September 4, 2025. Established by EURETINA in partnership with Oculis, the award honors the legacy of Professor Tadayoni, Oculis' former Chief Scientific Officer and a renowned retina specialist. This prestigious award promotes innovative research by recognizing an outstanding postgraduate scholar with the potential to make significant advances in understanding and treating retinal diseases.

Details of Oculis' presentations are as follows:

Ophthalmology Futures Retina Forum:

- *Is Diabetic Retinopathy the Overlooked Elephant in the Room – Panel Discussion*
  Presenter: Riad Sherif, M.D., Chief Executive Officer
  Date/Time: Wednesday, September 3, 2025; 10:00 – 10:30 CEST

- *Corporate Presentation*
  Presenter: Riad Sherif, M.D., Chief Executive Officer
  Date/Time: Wednesday, September 3, 2025; 14:00 CEST

EURETINA Innovation Spotlight:

- *Corporate Presentation*
  Presenter: Sharon Klier, M.D., Chief Development Officer
  Date/Time: Wednesday, September 3, 2025; 16:20 CEST

EURETINA:

- *Efficacy and Safety Outcomes over 12 weeks with OCS-01 Eye Drops in DME From DIAMOND Phase 2/3 trial: Focus on Subgroup by Lens Status*
  Presenter: Patricio Schlottmann, M.D.
  Session: Free Paper 1 - Diabetes & Vascular Diseases
  Date/Time: Thursday, September 4, 2025; 10:57 – 11:03 CEST

- *Efficacy and Safety Outcomes over 12 weeks with OCS-01 Eye Drops in DME From DIAMOND-Stage 1 trial: Focus on Subgroup by Prior Treatment Status*
  Presenter: Veeral Sheth, M.D., MBA, FACS, FASRS
  Session: Free Paper 1 - Diabetes & Vascular Diseases
  Date/Time: Thursday, September 4, 2025; 11:03 – 11:09 CEST

- *Improved Low Contrast Visual Acuity and Reduction in Retinal Ganglion Cell Loss with Privosegtor in Acute Optic Neuritis: Results from a Multicenter Randomized Placebo-Controlled Double-Masked Trial*
  Presenter: Sophie Bonnin, M.D.
  Session: Euretina Session 7 - First Time Clinical Trials & Late Breaking Session
  Date/Time: Friday, September 5, 2025; 15:57 – 16:03 CEST

Retina Society Annual Congress:

- *Efficacy and Safety Outcomes Over 12 Weeks with OCS-01 Eye Drops in DME from DIAMOND Phase 2/3 Trial: Focus on Subgroup by Lens Status*

Presenter: Diana Do, M.D.
Session: Diabetes 1
Date/Time: Thursday, September 11, 2025; 16:42 – 16:47 CDT

Sophie Bonnin, MD is the Deputy Head of the Retina Department at the Rothschild Foundation Hospital, specializing in retinal diseases, neuro-ophthalmology, and clinical imaging. She has authored over 50 medical and scientific articles and is actively involved in numerous research projects encompassing retinal imaging, diabetic retinopathy, myopia, and optic neuropathies.

Diana Do, MD is Professor of Ophthalmology and Vice Chair for Clinical Affairs at the Byers Eye Institute, Stanford University, where she also serves as Clinic Chief of Ophthalmology at Stanford Health Care. A leading surgeon-scientist, she has authored over 200 publications, received numerous national awards including the Heed Ophthalmic Foundation Clinician-Scientist Award and continues her active clinical practice while investigating novel treatments for retinal diseases and leading quality improvement initiatives at Stanford.

Patricio Schlottmann, MD is the Director of the Research Department at Charles Ophthalmic Center and the Ophthalmology Department Director at Organización Médica de Investigación in Buenos Aires, Argentina. A distinguished ophthalmologist, he has authored more than 60 scientific publications and serves on the Executive Committee for the Argentinean Vitreous Retina Society, advising global industry stakeholders.

Veeral Sheth, MD, MBA, FACS, FASRS is a Partner and Director of Clinical Trials at University Retina and Macula Associates. He also serves as a Clinical Assistant Professor at the University of Illinois at Chicago, where he specializes in diseases of the retina and vitreous. He is actively engaged in clinical research on age-related macular degeneration, retinal vascular occlusion, and diabetic retinopathy and has published extensively in peer-reviewed journals.

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 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 Privosegtor (OCS-05)

Privosegtor is a novel peptoid small molecule candidate with the potential to become a first-in-class neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases. The recent positive topline results in the ACUITY Phase 2 trial showed Privosegtor (OCS-05)'s neuroprotective benefits in anatomical preservation of the retina and visual function improvements in patients suffering from acute optic neuritis. Consistent results were observed in animal models of neuroinflammation and neurodegeneration where Privosegtor showed preservation of retinal ganglion cell damage and was associated with improvements in mobility (clinical function disability). Privosegtor has received orphan drug designation from both the FDA and the EMA for acute optic neuritis. In addition to this indication, a neuroprotective treatment could potentially have wide applicability in neuro-ophthalmic and neurology indications.

Privosegtor is an investigational drug in Phase 2 and has not received regulatory approval for commercial use in any country.

About Acute Optic Neuritis

Acute optic neuritis is a rare condition characterized by an acute inflammation of the optic nerve that can lead to permanent visual impairment. It affects up to 8 in 100,000 people worldwide and often represents the first sign of multiple sclerosis[3]. It mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1)[4]. The acute inflammatory process of acute optic neuritis leads to the loss of myelin covering the optic nerve and the axons. At the onset, patients often suffer from ocular pain that increases with eye movement and vision loss. Once the inflammation recedes, remyelination often occurs but it is incomplete. Without the myelin sheath protecting the axon, neurons located in demyelinated segments become fragile and prone to death. Unfortunately, damaged axons cannot regrow, leading to permanent visual impairment. To date there is no specific neuroprotective therapy approved for acute optic neuritis and unmet needs remain for therapies that can prevent vision loss after an acute episode of optic neuritis.

About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) focused on innovations addressing ophthalmic and neuro-ophthalmic conditions with significant unmet medical needs. Oculis' highly differentiated late-stage clinical pipeline includes three core product candidates: OCS-01, an eye drop in pivotal registration studies, aiming to become the first non-invasive topical treatment for diabetic macular edema; Privosegtor (OCS-05), a neuroprotective candidate in Phase 2 for acute optic neuritis, with potentially broad clinical applications in various retinal, neuro-ophthalmological and neurological diseases; and Licaminlimab (OCS-02), a novel topical anti-TNFα in Phase 2, being developed with a genotype-based approach to drive personalized medicine in dry eye disease. 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

(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
(3) Martínez-Lapiscina EH, et al. (2014): Is the incidence of optic neuritis rising? Evidence from an epidemiological study in Barcelona (Spain) 2008-2012. *J Neurol*. 2014 Apr; 261(4): 759-767.
(4) Pérez-Cambrodí RJ, Gómez-Hurtado Cubillana A, Merino-Suárez ML, Piñero-Llorens DP, Laria-Ochaita C. Optic neuritis in pediatric population: a review in current tendencies of diagnosis and management. J Optom. 2014 Jul-Sep;7(3):125-30.

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 and Privosegtor (OCS-05), including patient impact and market opportunity; the potential of OCS-01 to transform the treatment paradigm in diabetic macular edema as a non-invasive topical treatment option; the potential of Privosegtor (OCS-05) to become a first-in-class neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases; the initiation, timing, progress and results of Oculis' clinical trials; Oculis' research and development programs, regulatory and business strategy and future development plans; and Oculis' ability to advance product candidates into, and successfully complete, clinical trials, 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 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.

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