Oculis to Present its Innovative Late-Stage Pipeline Candidates at Upcoming Ophthalmology Conferences

May 1, 2025

ZUG, Switzerland, May 01, 2025 (GLOBE NEWSWIRE) -- 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 upcoming presentations highlighting its innovative late-stage pipeline at Eyecelerator 2025, the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and the Retina World Congress (RWC).

The presentation of the DME AWARE Delphi Study interim results will highlight key areas of consensus on unmet needs in DME patient management among leading global experts. Further insights from Stage 1 of the Phase 3 DIAMOND program reinforcing the efficacy and safety profile of OCS-01 eye drops for DME will also be shared. OCS-01 is being developed to be the first non-invasive treatment for DME, addressing key unmet needs for earlier treatment intervention and for inadequate responders to the current standard of care.

Data from the Phase 2b RELIEF trial investigating Licaminlimab (OCS-02) in signs of DED will be presented following positive and consistent results from phase 2 trials in symptoms. The genetic biomarker, previously identified, to predict response to Licaminlimab, enables the first genotype-based development plan to drive a personalized approach in dry eye disease (DED). Licaminlimab is being developed to transform the treatment paradigm in DED, currently driven by trial and error, and address unmet medical needs for this multifactorial disease with a dissatisfied patient population.

Details of the presentations are as follows:

Eyecelerator 2025

- *Company showcases – Retina: TKI and Drug Delivery*
  Presenter: Sharon Klier, M.D., Chief Development Officer
  Date/Time: Friday, May 2, 2025, 1:30 PM – 3:00 PM MST

ARVO Annual Meeting 2025

- *Interim results of the DME AWARE Delphi Study on unmet needs in DME patient management*
  Presenter: Anat Loewenstein, M.D., MHA
  Session: #261
  Presentation: #2587
  Posterboard: #B0300
  Date/Time: Monday, May 5, 2025, 3:00 PM – 4:45 PM MST

- *BCVA and CST Improvement over 12 weeks with OCS-01 Eye Drops in DME from DIAMOND Stage 1 trial*
  Presenter: Carl Danzig, M.D.
  Session: 401
  Presentation: #4011
  Location: Room #255ABC
  Date/Time: Wednesday, May 7, 2025, 10:15 AM – 12:00 PM MST

- *Licaminlimab in the treatment of dry eye disease*
  Presenter: Anat Galor, M.D., MSPH
  Session: #513
  Presentation: #5682
  Posterboard: #B0077
  Date/Time: Thursday, May 8, 2025, 8:00 AM – 9:45 AM MST

Retina World Congress 2025

- *Wet AMD, DR, RVO – Part 2, Panel Discussion*
  Participant: Riad Sherif, M.D., Chief Executive Officer
  Date/Time: Thursday, May 8, 2025, 11:25 AM – 11:59 AM ET

- *BCVA and CST Improvement over 12 weeks with OCS-01 Eye Drops in DME From DIAMOND-Stage 1 trial*
  Presenter: David Almeida, M.D., PhD
  Date/Time: Thursday, May 8, 2025, 6:08 PM – 6:13 PM ET

Anat Loewenstein, M.D., MHA, is Professor and Head of Retina, Division of Ophthalmology Tel Aviv Medical Center, VP Ambulatory Services Tel Aviv Medical Center, Sidney Fox Chair of Ophthalmology at the Sackler Faculty of Medicine at Tel Aviv University, and President of the EURETINA. In addition to being a member of Oculis’ DIAMOND Steering Committee, Dr. Loewenstein serves as a member of Oculis’ Scientific Advisory Board. Her main field of interest is the investigation of drug administration and toxicity to the retina, early detection of macular degeneration and home monitoring of retinal disease. She currently serves as the Editor in Chief of the Journal Case Reports in Ophthalmology, is an associate editor of Investigative Ophthalmology & Visual Science Journal, European Journal of Ophthalmology, and of Ophthalmologica. Professor Loewenstein published more than 500 papers in peer reviewed journals and contributed multiple chapters to ophthalmology textbooks. She is also actively involved as a leader in mentorship programs for young retina specialists including the mentorship educational programs of ARVO and EURETINA.

Carl Danzig, M.D., is the Director of Vitreoretinal Services and Retina Clinical Research at Rand Eye Institute in Deerfield Beach, FL, where he has been practicing since September 2011. In private practice, he founded the retina department at Rand Eye Institute and served as Principal Investigator in dozens of clinical trials. In addition, Dr. Danzig has frequently presented his research at various international ophthalmology meetings. He is also an Affiliate Assistant Professor of Clinical Biomedical Science at the Charles E. Schmidt School of Medicine at Florida Atlantic University in Boca Raton, FL. Recently, Dr. Danzig completely five years serving on the ONE network, retina division for the American Academy of Ophthalmology. Dr. Danzig spent his undergraduate years in New Orleans, LA at Tulane University, receiving a B.A. in Philosophy in 2000. He returned to his hometown for medical school at Temple University and stayed in Philadelphia for his internship along with a year of ocular oncology research at Wills Eye Hospital. Dr. Danzig completed his residency in ophthalmology at SUNY-Downstate Medical Center in Brooklyn, NY and went on to fellowship training in vitreoretinal surgery at University of Texas-Southwestern Medical Center in Dallas, TX.

Anat Galor, M.D., is a cornea and uveitis trained specialist with a dual appointment at the Bascom Palmer Eye Institute and the Miami VA medical center. Dr. Galor completed an ophthalmology residency at the Cole Eye Cleveland Clinic, a uveitis fellowship at the Wilmer Eye Institute, and a cornea and external diseases fellowship at Bascom Palmer Eye Institute. Dr. Galor currently runs the ocular surface program at the Miami VA and has focused her research on understanding mechanisms of pain in dry eye, with an emphasis on studying new diagnostic and treatment modalities. Some of her research focused on how ocular surface symptoms, including pain, affect the quality of life. She has brought to light the role of nerve dysfunction in dry eye and has developed novel diagnostic and therapeutic metrics to address dry eye symptoms and ocular pain due to nerve sensitization. She first demonstrated that symptoms and signs of dry eye were often discordant. This observation prompted her to study whether nerve dysfunction was the missing link between the observed discordance. She demonstrated that many symptoms of dry eye, such as burning and sensitivity to wind and light, were shared with chronic pain conditions outside the eye. She has published her work in high-impact ophthalmology and pain journals. Dr. Galor was named to The Ophthalmologist Power List 2021.

David R.P. Almeida, M.D., M.BA., Ph.D., FRCSC, DABO, is a highly accomplished vitreoretinal surgeon and researcher with extensive experience in ophthalmic and vitreoretinal studies. As Executive Chairman of Erie Retina Research and The Centers for Advanced Surgical Exploration (CASEx), Dr. Almeida leads innovative clinical research initiatives across multiple international sites. Dr. Almeida is a recognized thought leader in the field with over 300 peer-reviewed publications and more than 125 presentations at major conferences. His research interests span age-related macular degeneration, diabetic eye disease, complex surgery, and practice efficiency. As Principal Investigator, he has led over 100 clinical trials across all phases of development on three continents. Recognized for his expertise, Dr. Almeida has received numerous awards, including the American Society of Retina Specialists (ASRS) Honor Award, and has been named to The Ophthalmologist Power List Top 50 Rising Stars in Ophthalmology. Dr. Almeida's academic background includes an Honors Bachelor of Science from the University of Toronto, a Ph.D. in pharmaceutical research from the University of Szeged, and an MBA in healthcare management from George Washington University. He completed medical school (Queen's University, Canada), ophthalmology residency (Queen's University, Canada), and a vitreoretinal diseases and surgery fellowship (University of Iowa, USA).

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 Licaminlimab (OCS-02)

Licaminlimab is an anti-TNFα eye drop candidate being developed with a single chain antibody fragment (scFv) technology specifically designed to treat ocular inflammatory diseases. The dual anti-inflammatory and anti-necrotic mechanism of action of TNF-α inhibition has been well-established in inflammatory disorders where the systemic use of TNF-α inhibitors has led to marked improvements in the disease management and treatment outcomes. In Phase 2 trials, Licaminlimab has shown a positive treatment effect on both the signs and symptoms of DED and has been well tolerated. In addition, a genetic biomarker has been identified which showed an improved response to Licaminlimab in patients with a variant in the TNFR1 gene.

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

About Dry Eye Disease (DED)

DED is a common condition estimated to impact more than 110 million people in the G7 countries (U.S., U.K., Germany, France, Spain, Italy, Japan) and 40 million people in the U.S. alone[3]. It is a multifactorial disease in which ocular surface inflammation plays a central role in sustaining the pathological state[4,5]. It usually affects both eyes and patients may experience a stinging, burning or scratchy sensation. In addition, some patients experience sensitivity to light, eye redness, difficulty wearing contact lenses, difficulty with nighttime driving, and blurred vision which can greatly affect their quality of life.

Of the approximately 20 million patients who are diagnosed with DED in the U.S., about half or 10 million are considered to have moderate to severe disease[3]. However, only 13% receive prescription treatment, primarily with an anti-inflammatory medications[3]. Despite currently available treatments, 87% of chronic patients still unsatisfied[6] highlighting the tremendous unmet need remaining in this underserved patient population. Furthermore, given the heterogenicity of the DED patient population, there is a need for personalized treatment approaches to improve outcomes for patients.

About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS / XICE: OCS) focused on innovations addressing ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs. 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

Oculis Contacts
Ms. Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Investor Relations
LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com

Media Relations
ICR Healthcare
Amber Fennell / David Daley / Sean Leous
oculis@icrhealthcare.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 and Licaminlimab (OCS-02), including patient impact and market opportunity; the potential of OCS-01 to transform the treatment paradigm in DME as a non-invasive topical treatment option; the potential of Licaminlimab (OCS-02) to transform the treatment paradigm in DED; 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.

(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) DRG (part of Clarivate) – Dry Eye Disease Landscape and Forecast report 2020
(4) TFOS DEWS II The Ocular Surface 15 (2017)
(5) Baudouin C. Dry Eye Disease, the complex interactions of vicious cycles. EuDES European Dry Eye Society https://www.dryeye-society.com/resources/dry-eye-disease-complex-interactions-vicious-cycles
(6) Mukamal, R. Why is Dry Eye So Difficult to Treat? 2021 https://www.aao.org/eye-health/tips-prevention/fix-dry-eye-treatment-eyedrops