Positive Phase 3 Stage 1 DIAMOND Trial Results of OCS-01 in Diabetic Macular Edema Presented at 23rd EURETINA Congress

October 10, 2023 10:30 AM EDT

- *OCS-01's positive results in Stage 1 of the Phase 3 DIAMOND trial for diabetic macular edema (DME) were presented as a late-breaking abstract showing that the trial met primary and secondary endpoints with robust statistical significance*
- *On track to commence Stage 2 of the DIAMOND program with two parallel global Phase 3 trials*
- *If approved, OCS-01 has the potential to become the first topical eye drop for the treatment of DME*

ZUG, Switzerland and BOSTON, Oct. 10, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced that Professor Ramin Tadayoni, M.D., Ph.D., presented the positive results from Stage 1 of the Phase 3 DIAMOND trial of OCS-01 in patients with DME at the 23rd EURETINA congress, which took place October 5-8, 2023 in Amsterdam, the Netherlands.

Professor Tadayoni, who also chaired the "Landmarks and Late Breakings" session, presented data from the Stage 1 of the DIAMOND Phase 3 program showing that the trial met primary and secondary endpoints with robust statistical significance, and achieved its objective of confirming the loading and maintenance dose to be tested in Stage 2 of the trial. Specifically, the trial met its primary endpoint, showing a statistically significant improvement in Best Corrected Visual Acuity (BCVA) in patients treated with OCS-01versus vehicle-treated patients at Week 6 (OCS-01: 7.2 letters vs vehicle: 3.1 letters, p=0.007), which was sustained through Week 12 (OCS-01: 7.6 letters vs vehicle: 3.7 letters, p=0.016). For two secondary endpoints, a significantly higher percentage of patients treated with OCS-01 achieved ≥15-letter improvement in BCVA (OCS-01 25.3% vs vehicle: 9.8%, p= 0.015), and patients in the OCS-01 treatment arm also showed significant improvement in retinal thickness as compared to vehicle (OCS-01: -63.6 µm vs vehicle: +5.5 µm, p<0.0001). OCS-01 was well-tolerated with no unexpected adverse events observed. The positive results support the progression of the DIAMOND program, with two parallel 52-week global Phase 3 trials. If approved, OCS-01 has the potential to become the first topical eye drop for the treatment of DME and address the current treatment gap by providing a non-invasive therapeutic option.

Ramin Tadayoni, M.D., Ph.D., Professor of Ophthalmology, Université Paris Cité, France, and Department Head at Lariboisière, Saint Louis and Adolphe de Rothschild Foundation hospitals, and Co-chair of Oculis' Scientific Advisory Board, commented: "The results from the DIAMOND Phase 3 Stage 1 trial are exciting and very meaningful for both clinicians and patients with DME, the leading cause of visual loss and legal blindness in patients with diabetes. Current injectable treatments are linked to a high treatment burden, therefore having a non-invasive, topical treatment such as OCS-01 would represent a paradigm shift in how and when DME could be treated in the future."

Riad Sherif, M.D., Chief Executive Officer of Oculis, said: "We are honored that results from the DIAMOND Phase 3 Stage 1 trial of OCS-01 were selected as a late-breaking abstract for presentation at EURETINA, one of the top global congresses for cutting-edge retina science. We are committed to advancing sight saving treatments such as OCS-01 and remain on track to commence Stage 2 of the DIAMOND trial by the end of 2023."

OCS-01 is Oculis' lead product candidate and the first investigational eye drop for both front and back of the eye indications, with positive topline results in Stage 1 of the Phase 3 DIAMOND trial for diabetic macular edema (DME) announced in May 2023, and positive topline Phase 3 OPTIMIZE trial results for the treatment of inflammation and pain following cataract surgery announced in August 2023. Furthermore, the investigator-initiated LEOPARD study evaluating OCS-01 for treatment of cystoid macular edema (CME) enrolled its first patient in August 2023.

Leveraging Oculis' proprietary Optireach® technology, OCS-01 is a novel, high concentration (15 mg/ml), topical formulation of dexamethasone. It is developed to reach the retina via an eye drop, a route of administration for DME that is differentiated from currently available therapies, that are all invasive such as ocular implants or intravitreal injections to deliver the medication to the retina.

For more information about EURETINA 2023 visit: https://euretina.org/amsterdam-2023/information/

About Diabetic Macular Edema (DME)

DME is the leading cause of vision 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. DME is an irreversible and progressive complication of diabetic retinopathy and is related to consistently 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 leak, leading to a fluid build-up (edema) into the retina. There remains a significant need for safer, more effective, longer lasting, and less burdensome treatments for DME patients.

About Oculis

Oculis (Nasdaq: OCS) is a global biopharmaceutical company purposefully driven to save sight and improve eye care. Oculis' highly differentiated clinical-stage pipeline comprises multiple innovative product candidates in development for eye diseases of high unmet need. It includes OCS-01 eye drops, a topical candidate in Phase 3 development for diabetic macular edema (DME) and inflammation and pain following ocular surgery; OCS-02 eye drops, a topical biologic candidate in Phase 2 development for dry eye disease (DED) and uveitis; and OCS-05, a disease modifying candidate for acute optic neuritis (AON) and other neuro-ophthalmic disorders, such as glaucoma, diabetic retinopathy, geographic atrophy, and neurotrophic

keratitis. The first in-patient, proof-of-concept trial with OCS-05 is currently ongoing in France. Headquartered in Switzerland and with operations in the US, Oculis' goal is to deliver life-changing eye treatments to patients worldwide. The Company is led by an experienced management team with a successful track record in the pharmaceutical industry, supported by leading international healthcare investors.

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

Oculis Contacts

Mrs. Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Investor & Media Relations

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com
1-212-915-2577

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; expectations for Stage 2 of the DIAMOND program; the potential for OCS-01 to become the first non-invasive, topical eye drop for the treatment of DME; the potential for OCS-01 to become the first eye drop for both front and back of the eye indications; the potential of OCS-01 for the treatment of DME and inflammation and pain following ocular surgery; the potential of OCS-01 for the treatment of CME; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical and preclinical studies; 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.

Source: Oculis Holding AG