Oculis Announces Positive Top Line Results from DIAMOND Stage 1 Phase 3 Trial in Diabetic Macular Edema with OCS-01 Eye Drops

May 22, 2023

- *DIAMOND trial in Diabetic Macular Edema (DME) with topical OCS-01 met its stage 1 objective of validating the loading and maintenance dosing regimen designed to optimize OCS-01 efficacy potential with robust statistical significance*
- *Primary efficacy endpoint of mean change in Best Corrected Visual Acuity (BCVA) versus baseline at Week 6 showed statistically significant increase in visual acuity in the OCS-01 arm compared to vehicle arm*
- *Statistically significant secondary endpoints showed higher percentage of patients achieving ≥15-letter improvement in BCVA and better improvement in retinal thickness in the OCS-01 arm versus vehicle arm*
- *OCS-01 was well-tolerated with no unexpected adverse events observed*
- *If approved, OCS-01 has the potential to become the first topical and non-invasive treatment for DME*
- *An investor and analyst call will be held today at 8:00am US Eastern Time, details below*

ZUG, Switzerland and BOSTON, May 22, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced positive top line results from Stage 1 of its Phase 3 DIAMOND trial of OCS-01 eye drops in Diabetic Macular Edema (DME). DME is the leading cause of visual loss and legal blindness in patients with diabetes, affecting around 37 million people worldwide, with a significant number of patients left untreated due to a lack of convenient treatment options.

OCS-01 Positive Phase 3 Stage 1 Top Line Results Could Signify a Paradigm Shift in DME

DIAMOND (DIAbetic Macular edema patients ON a Drop) is a Phase 3, two-stage, double-masked, randomized, multi-center trial to assess the efficacy and safety of OCS-01 eye drops in DME patients. The primary objective of Stage 1 was to select the optimal dosing regimen. Stage 1 was conducted in 39 sites across the USA and Europe with 148 patients randomized 2:1 to receive OCS-01 (n=100) or vehicle (n=48) six times daily for a six-week loading phase and then three times daily for a subsequent six-week maintenance phase.

Stage 1 met the primary efficacy endpoint with a statistically significant improvement in mean BCVA "Early Treatment Diabetic Retinopathy Study" chart (BCVA ETDRS) score from baseline to Week 6 versus (vs) vehicle (OCS-01: 7.2 letters vs vehicle: 3.1 letters, p=0.007) demonstrating strong visual gain in the treatment arm. The effect was sustained to Week 12 with statistical significance (OCS-01: 7.6 letters vs vehicle 3.7 letters, p= 0.016). Furthermore, there was a higher percentage of patients in the OCS-01 group who achieved ≥15-letter improvement in BCVA from baseline vs vehicle at Week 6 (OCS-01: 25.3% vs vehicle: 9.8%, p=0.015), which was sustained to Week 12 (OCS-01: 27.4% vs vehicle 7.5%, p=0.009).

OCS-01, in this 3-month trial, has met both clinical efficacy endpoints (main BCVA change, proportion of patients with 3 lines gain) that are required for regulatory approval, if met at 12 months treatment duration.

An effect on retinal thickness was also observed with a statistically significant decrease in Central Subfield Thickness (CST) at Week 6 versus baseline in the OCS-01 treatment arm (OCS-01: -63.6 µm vs vehicle: +5.5 µm, p<0.0001). The decrease in retinal thickness persisted to Week 12 (-61.6 µm vs -16.0 µm, p=0.004).

OCS-01 was well-tolerated with no unexpected adverse events observed.

The OCS-01 development program will continue as planned with Stage 2 which includes two global trials, each enrolling approximately 350-450 patients. Oculis expects to begin Stage 2 of the DIAMOND trial in the second half of this year.

Riad Sherif, M.D., CEO of Oculis, said: *"I am pleased and very encouraged that in Stage 1 of this trial, OCS-01 has met both primary and secondary endpoints in a robust and statistically significant manner. A topical agent has never demonstrated a positive result in DME. Now, OCS-01 has been validated in two different studies with consistent and repeated positive results. We remain focused on advancing with high priority the DIAMOND Phase 3 trial to Stage 2. This important milestone has the potential to bring us one step closer to providing the first treatment in the form of eye drops to patients with DME which is a devastating and blinding disease."*

Arshad M. Khanani, M.D., M.A, Director of Clinical Research at Sierra Eye Associates and Clinical Associate Professor at University of Nevada, Reno School of Medicine, Reno, Nevada and Co-Principal Investigator for the DIAMOND trial, commented: *"As a co-principal investigator of the Phase 3 DIAMOND trial, it is exciting to see the positive Stage 1 results from this trial. A 7.2 letters improvement in BCVA and a 63.6 µm reduction in CST at 6 weeks after initiating topical treatment with OCS-01 in patients with DME is clinically meaningful for treating physicians and patients. As a non-invasive treatment that has shown these positive results, OCS-01 has the potential of benefitting a large number of patients with DME if approved. I am looking forward to enrolling patients in Stage 2 of this trial.*"

David S. Boyer, M.D., Adjunct Clinical Professor of Ophthalmology, Keck School of Medicine, University of Southern California, Los Angeles and Co-Principal Investigator for the DIAMOND trial, said: *"The mechanism of DME involves both increased permeability and inflammation. Current anti-VEGFs are effective as anti-permeability agents but have no effect on inflammation. Therefore, a significant proportion of patients are sub-optimally treated with anti-VEGFs alone. If approved, OCS-01 has the potential to complement current treatment and address recalcitrant patients. Furthermore, since it is a topical agent, it has also the potential to be a first line treatment in DME, if approved. In short, I believe the impact of OCS-01 in DME could be a true game-changer."*

About OCS-01 eye drops and the OPTIREACH® technology

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 in contrast with currently available therapies, all requiring the

use of more invasive treatments such as ocular implants or intravitreal injections to deliver the medication to 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.

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 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 safer, more effective, longer lasting, and less burdensome treatments for DME patients.

Analyst and Investor Call
The Oculis management team will host an analyst and investor call on Monday, May 22nd at 8:00 am US Eastern Time to discuss the news. During the event, the Oculis management team will present the results of Stage 1, **Pravin Dugel, M.D.** (USA) will moderate questions and both co-principal investigators for the DIAMOND trial, **Arshad M. Khanani, M.D.** (USA) and **David S. Boyer, M.D.**, (USA) will be present to answer clinical questions during the live Q&A session.

To access the live event online, please pre-register for the webcast here. To access the live event by phone, please pre-register for the conference call here. 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 (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, Europe, and China, 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

(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

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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; expectations for Stage 2 of the DIAMOND trial; the potential for OCS-01 to become the first topical and non-invasive treatment for DME; the potential for OCS-01 to complement anti-VEGF treatment; 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. The clinical data presented herein is preliminary and is subject to change, as analysis is ongoing. These results may not be reproduced in subsequent patients and clinical trials. 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' filings 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.