OCS-01, First Investigational Eye Drop for Front and Back of the Eye, Met Both Primary Endpoints in Phase 3 OPTIMIZE Trial with a Once Daily Regimen for the Treatment of Inflammation and Pain Following Cataract Surgery

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- *Once daily OCS-01 meets primary endpoints demonstrating superior reduction in inflammation and pain vs. vehicle following cataract surgery*
- *OPTIMIZE's results follow the positive and statistically significant top line results from stage 1 of the Phase 3 DIAMOND trial in Diabetic Macular Edema (DME) reported earlier this year, further highlighting the product's potential for treating front- and back-of-the-eye diseases*
- *If approved, OCS-01 has the potential to become a new standard of care as the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery*
- *An investor and analyst call will be held today at 8:00am US Eastern Time, details below*

ZUG, Switzerland, and BOSTON, Aug. 08, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, announced today positive top line results from its Phase 3 OPTIMIZE trial with OCS-01 eye drops, a novel, once-daily, high concentration, preservative-free, topical OPTIREACH® formulation of dexamethasone for the treatment of inflammation and pain following ocular surgery.

Positive Phase 3 Results Show Potential for Once-Daily Treatment following Ocular Surgery

OPTIMIZE (**O**nce-daily **P**ost-ocular surgery **T**reatment for **I**nfla**M**mation and pa**I**n to minimi**ZE** drops) is a double-blind, placebo-controlled Phase 3 trial conducted in 25 sites across the US with 241 patients randomized 1:1 to receive once daily (QD) OCS-01 eye drop (n=119) or vehicle (n=122) for fourteen (14) days following cataract surgery.

The trial met both hierarchical primary efficacy endpoints, the absence of inflammation at Day 15 and the absence of pain at Day 4, with robust statistical significance:

- **Inflammation**: the percentage of eyes with zero inflammation (absence of anterior chamber cells, score = 0) was statistically significantly greater with OCS-01 QD compared with vehicle at Day 15 (OCS-01, 57.2% vs vehicle, 24.0%, p<0.0001).

- **Pain**: the percentage of eyes with zero pain (absence of pain, score = 0) was statistically significantly greater with OCS-01 QD compared with vehicle at Day 4 (OCS-01, 75.5% vs vehicle, 52.0%, p<0.0001).

Furthermore, OCS-01 was well tolerated with a favorable safety profile. Overall, a higher number of ocular treatment emergent adverse events (TEAEs) were reported for the vehicle group (n=84) compared with the OCS-01 QD group (n=37). There was no meaningful difference in intraocular pressure (IOP) between treatment groups with a mean change from baseline to Day 15 of -0.90 mmHg in both the OCS-01 group and the vehicle group.

OPTIMIZE results in reduction of inflammation and pain and safety observations were consistent with those observed in the Phase 2 SKYGGN trial with once daily administration. In the SKYGGN trial, the same two hierarchical primary efficacy endpoints were also met with robust statistical significance and with similar numerical values.

If approved, OCS-01 has the potential to become a new standard of care and the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery.

The Phase 3 OPTIMIZE positive top line readout with OCS-01 once daily eye drops in inflammation and pain following ocular surgery follows the statistically significant top line results of OCS-01 from stage 1 of the Phase 3 DIAMOND trial in Diabetic Macular Edema (DME) reported earlier this year, further highlighting the product's potential for treating front- and back-of-the-eye diseases. The results also follow the initiation of the LEOPARD investigator-initiated trial evaluating the potential of OCS-01 for the treatment of Cystoid Macular Edema, one of the most significant causes of vision loss following cataract surgery.

***Eric Donnenfeld MD, Co-chair of Oculis' Scientific Advisory Board, said**: "The results of the Phase 3 OPTIMIZE trial are exciting because once daily OCS-01 showed to be superior and highly potent in reducing inflammation and pain compared to vehicle with a favorable safety profile. This is significant for patients who have undergone cataract surgery, as they currently need to self-administer multiple daily doses of eye drops to alleviate*

inflammation and pain. The availability of a preservative-free treatment that requires only a once-daily eye drop could greatly benefit a large number of patients who undergo ocular surgeries worldwide."

***Riad Sherif MD, Chief Executive Officer of Oculis, commented**: "I am very pleased with the positive readout of OPTIMIZE. A once daily topical steroid eye drop has shown solid results in reduction of inflammation and pain and offers the potential of a truly simplified dosing regimen. We are on track to advance OCS-01 for inflammation and pain following ocular surgery towards an NDA submission with FDA. We now have positive Phase 3 top line results with OCS-01 preservative-free eye drops in treating front-of-the-eye inflammation and pain following ocular surgery, as well as Stage 1 Phase 3 results for back-of-the-eye diabetic macular edema (DME) from the DIAMOND program, opening for the first time ever new opportunities for topical eye drops to address highly unmet patient needs in both front- and back-of-the-eye indications."*

About inflammation and pain post ocular surgery

Due to the aging population, lifestyle changes and several other factors, ophthalmic surgical procedures are on the rise and are expected to reach close to 10 million procedures per year in the US alone by 2037[1,2]. Cataract surgeries are the most prevalent procedures of all medical specialties with an estimated 5.3 million procedures in 2021 for the US alone[2]. Ophthalmic procedures promote the release of inflammatory factors and can be associated with ocular pain. Cataract surgery, while the incision is very small, creates inflammation in the cornea, anterior chamber, and iris. Ophthalmologists currently rely on topical steroids to treat ocular inflammation and the full regimen following ocular surgery often includes steroids, antibiotics and NSAID, which can require several drops daily for a post-op patient to self-administer, which may lead to compliance issues.

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. 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 less frequent administration for front-of-the-eye and the drug passage from the eye surface to the posterior segment for back-of-the-eye diseases.

Analyst and investor call

The Oculis management team will host an analyst and investor call today at 8:00 am US Eastern Time, to review the trial results. The principal investigator for the OPTIMIZE trial, Michael Korenfeld, M.D. (USA) and Eric Donnenfeld, 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.

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.

[1] 2016 HCUP procedure volume and growth rate, and corroborated by Rochester Epidemiology Project Paper. Third party market research.

[2] Meddevicetracker – Ophthalmic Surgical Products Market 2017.

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

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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; the potential of OCS-01 for treating front- and back-of-the-eye diseases; the potential for OCS-01 to become a new standard of care with the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery; the potential of OCS-01 for the treatment of Cystoid Macular Edema; 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