Oculis Announces First Patient First Visit in Phase 3 OPTIMIZE-2 Trial of OCS-01 for the Treatment of Inflammation and Pain Following Cataract Surgery

December 20, 2023 11:30 AM EST

- *Initiation of the second Phase 3 OPTIMIZE-2 trial with OCS-01 once daily eye drop, follows the recently reported positive OPTIMIZE-1 trial results*
- *OPTIMIZE-2 topline readout expected before end of 2024 to support NDA submission*
- *OCS-01 is also being evaluated as potentially the first topical eye drop treatment for Diabetic Macular Edema (DME) in the DIAMOND program and for the treatment of Cystoid Macular Edema (CME) in the LEOPARD trial*

ZUG, Switzerland, and BOSTON, Dec. 20, 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 First Patient First Visit (FPFV) in OCS-01 Phase 3 OPTIMIZE-2 trial for the treatment of inflammation and pain following cataract surgery. Data from the Phase 3 OPTIMIZE-2 trial is intended to support the Company's NDA submission to the Food and Drug Administration (FDA). If approved, OCS-01 has the potential to be the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery.

The OPTIMIZE-2 (**O**nce-daily **P**ost-ocular surgery **T**reatment for **I**nfla**M**mation and pa**I**n to minimi**ZE** drops) is a multi-center, randomized, double-masked, vehicle-controlled Phase 3 trial evaluating OCS-01 for the treatment of inflammation and pain following cataract surgery. Similar to the OPTIMIZE-1 trial, patients in the second Phase 3 OPTIMIZE-2 trial will be treated with once-daily OCS-01 post-cataract surgery versus vehicle for 2 weeks. Primary endpoints are the absence of anterior chamber cells (inflammation) on Day 15 and absence of pain on Day 4. The OPTIMIZE-2 trial follows the positive topline results from the OPTIMIZE-1 trial showing that OCS-01 increased the percentage of patients who were inflammation free at Day 15 and had zero pain at Day 4 vs. vehicle with statistical significance ($p<0.0001$ for both endpoints), and was well tolerated.

Moreover, the initiation of OPTIMIZE-2 follows the start of Stage 2 of the Phase 3 DIAMOND trial of OCS-01 in DME announced earlier this week, and the commencement of the investigator-initiated LEOPARD trial of OCS-01 in patients with CME announced earlier this year.

Riad Sherif, M.D., Chief Executive Officer of Oculis, remarked: "Initiation of the OPTIMIZE-2 trial preceded by the launch of OCS-02 RELIEF Phase 2b trial in dry eye, and OCS-01 DIAMOND-1 trial in DME in the past couple weeks, highlights our robust pipeline and ability to execute and deliver on commitments. This timely progress also underscores the steadfast advancement of the OCS-01 development program thus far, as well as OCS-01's potential as an eye drop treatment for both front- and back-of-the-eye diseases. We look forward to the important milestones expected in the year ahead, including four topline clinical readouts from OPTIMIZE-2 and the LEOPARD trials with OCS-01, the RELIEF trial with OCS-02, and from the ACUITY trial in Acute Optic Neuritis (AON) with OCS-05."

Eric Donnenfeld, M.D., Clinical Professor of Ophthalmology at New York University and Co-chair of Oculis Scientific Advisory Board, said: "I was excited to see the positive efficacy results and the favorable safety profile from the first Phase 3 OPTIMIZE trial and the consistency with the prior Phase 2 results. Once daily OCS-01 could become an attractive option to treat pain and inflammation after ocular surgery with a highly potent anti-inflammatory effect. This could be especially beneficial for high-risk patients, such as diabetic patients, who face an increased risk of complications following ocular surgery due to pre-existing underlying inflammation."

About inflammation and pain following ocular surgery
Ophthalmic surgeries are on the rise, mainly due to the aging population and lifestyle changes, and are expected to reach close to 10 million procedures per year in the U.S. alone by 2037[1,2]. Cataract surgeries are the most prevalent procedures of all medical specialties with an estimated 5 million procedures in 2021 in the US[2]. Ophthalmic surgeries cause the release of inflammatory factors and can be associated with ocular pain. Cataract surgery, even with a very small incision, 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 have a different dosing regimen and require several drops daily for a post-op patient to administer, all leading to potential 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.

[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 is a global biopharmaceutical company (Nasdaq: OCS) purposefully driven to save sight and improve eye care. Oculis' highly differentiated pipeline comprises multiple innovative product candidates in development. It includes OCS-01, a topical eye drop candidate for diabetic macular edema (DME) and for the treatment of inflammation and pain following cataract surgery; OCS-02, a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED) and for non-infectious anterior 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. Headquartered in Switzerland and with operations in the US, Oculis' goal is to deliver life-changing treatments to patients worldwide. The company 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 & 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; the potential of OCS-01 to be the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery; the potential of OCS-01 for treating front- and back-of-the-eye diseases; the potential of OCS-01 for the treatment of Diabetic Macular Edema (DME) and Cystoid Macular Edema (CME); expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical trials; 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