Oculis Completes Enrollment in Phase 3 OCS-01 OPTIMIZE Trial

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- *Completed enrollment in Phase 3 OPTIMIZE trial brings OCS-01 one step further on the regulatory path to approval.*
- *If approved, OCS-01 has the potential to become the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery.*
- *Significant progress made with OCS-01 (Oculis' lead clinical candidate) - additional results expected later this year from stage one of the Phase 3 DIAMOND trial in Diabetic Macular Edema (DME).*

LAUSANNE, Switzerland, March 16, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis") a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announces the completion of enrollment for its Phase 3 OPTIMIZE trial evaluating the efficacy and safety of once-daily OCS-01, a novel, high concentration, preservative-free, topical OPTIREACH formulation of dexamethasone for the treatment of inflammation and pain following cataract surgery.

The OPTIMIZE (**O**nce-daily **P**ost ocular surgery **T**reatment for **I**nfla**M**mation and pa**I**n to minimi**ZE** drops) trial is a randomized, double-blind, placebo-controlled Phase 3 trial in 25 participating sites across the US, with 240 patients. Efficacy measures include the absence of inflammation at Day 15 and absence of pain at Day 4.

In the completed Phase 2 SKYGGN study, OCS-01 met its primary and secondary endpoints of absence of anterior chamber cells and absence of pain, achieving statistical significance for patients who received once-daily dosing of OCS-01 vs vehicle in the treatment of inflammation and pain following cataract surgery. OCS-01 was also well tolerated in this trial. These data were presented at the American Society of Cataract and Refractive Surgery (ASCRS) 2020 Annual Meeting and published in *Clinical Therapeutics*. The study, "OCS-01 in Treating Inflammation and Pain in Post-cataract Patients (SKYGGN)", is accessible on the National Institutes of Health (NIH) website here.

The results from the SKYGGN Phase 2 trial showed OCS-01, administered once daily or twice daily, was more effective than vehicle with respect to the primary and secondary endpoints and well-tolerated in the treatment of inflammation and pain following cataract surgery. The once-a-day data from the trial demonstrated that OCS-01's unique formulation may allow for effective and safe once a day dosing. Once-daily administration of OCS-01 is expected to facilitate compliance, minimize instillation challenges, and eliminate confusion caused by complicated tapering schedules. In addition, reduced frequency of medication coupled with preservative-free preparations can improve the health of the ocular surface.

Riad Sherif MD, CEO of Oculis, said: *"Oculis has taken a material step forward in advancing OCS-01's Phase 3 clinical trial and I wish to congratulate everyone involved. I would like also to thank all our partners and investigators for their great commitment to clinical development. I am proud of the rapid progress we are making towards our goal of delivering life-changing innovative treatments to patients."*

Eric Donnenfeld, co-chair of Oculis' Scientific Advisory Board, commented: *"OCS-01 could bring significant therapeutic benefit as a once-daily treatment for inflammation and pain following ocular surgery. In addition, given its ability to reach the back of the eye, it could also offer further benefit in treating retinal edema, as shown in Oculis' DME Phase 2 trial and previous exploratory trial in CME, a significant complication following ocular surgery."*

OCS-01 is also being evaluated in another ongoing Phase 3 clinical trial, the DIAMOND study, as potentially the first topical treatment for diabetic macular edema (DME), if approved. It has been developed using Oculis' OPTIREACH technology, a proprietary platform that enables the formulation of drug candidates as topical eye drops with longer residence time on the eye surface, and enhanced bioavailability in the relevant eye tissues, including the retina.

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 retinal candidate for diabetic macular edema (DME); OCS-02, a topical biologic candidate for dry eye disease (DED); and OCS-05, a disease modifying candidate for acute optic neuritis (AON) and other neuro-ophtha disorders such as glaucoma, diabetic retinopathy, geographic atrophy, and neurotrophic keratitis. Headquartered in Switzerland and with operations in the US, Europe, and China, 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

Contacts

Investor Relations

Dr Riad Sherif, CEO
riad.sherif@oculis.com

Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Media Relations

Consilium Strategic Communications
Amber Fennell, Tracy Cheung, David Daley
oculis@consilium-comms.com or ir@oculis.com

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward looking statements and information. For example, statements regarding expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical and preclinical studies; the potential for OCS-01 to be the first approved topical treatment for the treatment of DME and inflammation and pain following ocular surgery; 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' final prospectus dated February 3, 2023, 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.