



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

- *Phase 3 OPTIMIZE trial initiation follows positive Phase 2 data and successful end-of-Phase 2 meeting with the U.S. FDA*
- *Potential to become the first once-daily, topical and preservative-free corticosteroid for treating inflammation and pain following ocular surgery*
- *In addition, Phase 3 DIAMOND trial of OCS-01 is ongoing in lead indication Diabetic Macular Edema (DME) with potential to become the first topical eye drop for a back of the eye disease*

Lausanne, Switzerland, June 29, 2022 – Oculis S.A., (Oculis) a global ophthalmology company developing life-changing treatments to save sight and improve eye care with breakthrough innovations, today announced that the first patient has been enrolled in its Phase 3 OPTIMIZE (Once-daily Post ocular surgery Treatment for Inflammation and pain to minimize drops) 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.

In the completed Phase 2 SKYGGN study, once-daily OCS-01 successfully met its primary endpoint demonstrating superior efficacy and safety vs vehicle (placebo) in the treatment of inflammation and pain following cataract surgery. Positive data from that trial was presented at the American Society of Cataract and Refractive Surgery (ASCRS) 2020 Annual Meeting. Oculis subsequently held a positive end-of-Phase 2 meeting with U.S. FDA which enabled the start of the Phase 3 OPTIMIZE trial.

OPTIMIZE is a randomized, double-blind, placebo-controlled Phase 3 trial in 25 participating sites across the US and is scheduled to enroll approximately 240 patients. Efficacy measures of the trial include the absence of anterior chamber cells at Day 15 and absence of pain at Day 4.

Treatment of inflammation and pain following ocular surgery is another indication being pursued for OCS-01, following the commencement in November 2021 of the Phase 3 DIAMOND trial investigating OCS-01 in patients with DME.

Eric Donnenfeld, M.D. clinical professor of ophthalmology at New York University and Trustee of Dartmouth Medical School, said: “Following cataract surgery, patients often need to self-administer eye drops several times a day to manage inflammation and pain. An efficacious, preservative-free alternative, administered just once a day could provide significant advantages over current options.”

Riad Sherif, M.D., CEO of Oculis, said: “This is another important development milestone for OCS-01, following the start of our Phase 3 trial in DME last year, which further signals the potential for this novel product candidate to address the limitations of currently available treatments for both retinal and front-of-the-eye indications. Clinical data generated so far have been very encouraging and we look forward to generating further data in this trial to support regulatory submissions.”

OCS-01 has been developed using Oculis's OPTIREACH solubilizing nanoparticle technology, a proprietary platform that enables the formulation of drugs as non-invasive topical eye drop treatments, a longer residence time on the eye surface and enhances their bioavailability in the relevant eye tissues, particularly the retina.

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About Oculis

Oculis is a global biopharmaceutical company purposefully driven to save sight, improve eye care and address significant unmet medical needs with breakthrough innovations. Oculis's highly differentiated pipeline includes candidates for topical retinal treatments, topical biologics and disease modifying treatments. With a presence in key international markets, Oculis is poised to deliver life-changing treatments to patients worldwide. Headquartered in Lausanne, Switzerland and with operations in Europe, the U.S. and China, Oculis is led by an experienced management team with a successful track record and supported by leading international healthcare investors.

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

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