First Patient Enrolled in LEOPARD, an Investigator-Initiated Trial, with OCS-01 Eye Drops for the Treatment of Cystoid Macular Edema

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- *LEOPARD trial initiation follows recent positive data from OCS-01 eye drops from the Stage 1 Phase 3 DIAMOND trial in patients with Diabetic Macular Edema (DME)*
- *Cystoid Macular Edema (CME) can result from uveitis or from post-surgical complications*
- *CME is one of the most significant causes of vision loss after ocular surgery[1] and approximately 28% of patients who undergo ocular surgery, including patients with diabetes, uveitis and other risk factors, have a higher risk of CME[2]. In addition, CME can also occur in about 40% of patients with posterior or pan-uveitis[3]*

ZUG, Switzerland, and BOSTON, Aug. 02, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, announces that the first patient has been enrolled in the investigator-initiated LEOPARD trial evaluating the potential of OCS-01 eye drops, Oculis' novel high concentration preservative-free topical OPTIREACH formulation of dexamethasone, for the treatment of cystoid macular edema (CME).

CME may occur as a complication of ocular conditions, including uveitis and ocular surgery, and is a leading cause of vision loss worldwide. It is one of the most significant causes of postoperative vision loss after cataract surgery[1]. Approximately 28% of patients who undergo ocular surgery, including patients with diabetes, uveitis and other risk factors, have a higher risk of developing CME following the procedure[2]. Up to 56% of high-risk patients may experience clinically significant CME following ocular surgery[1].

The LEOPARD trial, administratively sponsored by the Global Ophthalmic Research Center (Los Altos, California) and led by Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology at the Byers Eye Institute, Stanford University School of Medicine, aims to evaluate the efficacy and safety profile of OCS-01 eye drops in the management of two different forms of CME: Uveitic Macular Edema (UME) and Post-Surgical Macular Edema (PSME). It is a prospective, multi-center, open label, single-armed trial which plans on enrolling 24 eligible subjects (12 with UME and 12 with PSME). Two different doses will be used, and the total treatment period is 24 weeks. The primary endpoints, which will be assessed at 12 weeks, are improvement in central subfield thickness (CST) and visual acuity.

CME is being explored with OCS-01 eye drops, in addition to diabetic macular edema (DME) and inflammation and pain post ocular surgery, both indications currently in Phase 3 clinical development. OCS-01 has demonstrated its potential to reduce macular edema as measured by improvements in retinal thickness in a pilot study with uveitic macular edema patients as well as in the recently completed Stage 1 of the Phase 3 DIAMOND trial in patients with DME.

Professor Nguyen, who is a member of the Oculis Scientific Advisory Board, commented: "*I am very excited to investigate the potential of OCS-01 eye drops for the treatment of cystoid macular edema, one of the most common causes of decreased vision in patients following cataract and other ophthalmic surgeries, and in uveitis patients. Given the recently announced DIAMOND Phase 3 Stage 1 data readout in DME, which showed statistically significant reduction in retinal thickness with OCS-01, we believe in its potential to provide a paradigm shift in the treatment of post-surgical and uveitic macular edema, in addition to DME.*"

Riad Sherif, M.D., Chief Executive Officer of Oculis, concluded: *"Oculis is proud to support this investigator-initiated trial led by Professor Nguyen in cystoid macular edema with OCS-01 eye drops, to explore its potential in this vision-threatening eye condition. OCS-01 is Oculis' lead compound currently being investigated in two Phase 3 clinical trials in DME as well as inflammation and pain following with ocular surgery with promising efficacy and safety data."*

[1] Laura H.P. Wielders et al. Prevention of CME After Cataract Surgery, CRST Today Europe, 2013 https://crstodayeurope.com/articles/2013-julaug/prevention-of-cme-after-cataract-surgery

[2] Hennings et al. Prognostic determinants of postoperative pseudophakic macular oedema in a tertiary hospital setting ARVO Annual Meeting Abstract, June 2021, volume 62, Issue 8, https://iovs.arvojournals.org/article.aspx?articleid=2775475

[3] Oren Tomkins-Netzer et al. Seven-year outcomes of uveitic macular edema: the Multicenter Uveitis Steroid Treatment (MUST) Trial and Follow-up Study results, Ophthalmology, May 2021 128 (5): 719-728 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7943640/

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 retinal candidate for diabetic macular edema (DME); OCS-02, a topical eye drop 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, 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

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