Oculis completes patient recruitment for stage 1 of Phase 3 DIAMOND study evaluating the efficacy and safety of OCS-01 in Diabetic Macular Edema (DME)

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- **Oculis has completed enrollment for stage 1 of its Phase 3 DIAMOND study to evaluate the efficacy and safety of OCS-01 in DME**
- **The study will measure standard DME endpoints, such as mean change in BCVA ETDRS letters score and in macular thickness (CST, central subfield thickness) compared to baseline**
- **Prior to the initiation of the DIAMOND study, OCS-01 demonstrated efficacy and safety in a Phase 2b clinical trial in DME, offering the potential, if approved, to become the first topical eye drop and non-invasive treatment for DME which could improve patient access, reduce the burden on healthcare systems and improve patient outcomes**

LAUSANNE, Switzerland, January 5, 2023 – Oculis S.A., ('Oculis') a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announces the completion of enrollment for stage 1 of its Phase 3 DIAMOND (DIAbetic Macular edema patients ON a Drop) study evaluating the efficacy and safety of OCS-01 in patients with diabetic macular edema (DME).

At the end of 2021, Oculis launched its 2 stage Phase 3 DIAMOND study, a double-masked, randomized, vehicle-controlled, multi-center, multi-country study of OCS-01 in patients with DME. The primary endpoint of the trial, in both stages, is the mean change in the Best Corrected Visual Acuity "Early Treatment Diabetic Retinopathy Study" chart (BCVA ETDRS) from baseline to Week 6 (stage 1) and to Week 52 (stage 2). Several vision and anatomical secondary endpoints are also planned, including the mean change in macular thickness (CST, central subfield thickness) measured by SD-OCT (spectral domain optical coherence tomography) from baseline. More details can be found at www.clinicaltrials.gov – NCT05066997.

Leveraging Oculis' proprietary Optireach® technology, OCS-01 is a novel, high concentration, topical formulation of dexamethasone that has the potential to be the first topical eye drop and non-invasive treatment for DME. Oculis believes that OCS-01, if approved, could open up the possibility of treating DME patients via an eye drop, also offering prescribers the opportunity to provide customized treatment and maximize patient outcomes.

Riad Sherif, M.D., CEO of Oculis, said: *"I am delighted Oculis has completed patient enrollment for stage 1 of our DIAMOND study. It is a huge testament to our dedicated team who are now focused on completing the treatment phase and preparing for stage 1 data readout which is expected in mid-2023. This study is a critical step in our effort to develop a novel and more easily accessible treatment for DME patients that can help prescribers improve patients' eyesight and enhance their quality of life."*

David S. Boyer, M.D., Adjunct Clinical Professor of Ophthalmology, Keck School of Medicine, University of Southern California, Los Angeles and Co-Primary Investigator for the DIAMOND study, said: "*The ability to use a treatment with a topical route of administration would convey important advantages including an early and accessible treatment, greater convenience and less invasiveness. At present, OCS-01, developed using the proprietary Optireach® technology, seems to be one of the most promising drug candidates in Phase 3. If approved, it could be used as a standalone treatment of early DME or as an adjunctive therapy. An efficacious topical therapy may allow physicians to treat DME earlier and/or potentially combine it with the current standard of care to drive more efficacy or durability."*

Arshad M. Khanani, M.D., M.A, Director of Clinical Research at Sierra Eye Associates and Clinical Associate Professor at University of Nevada, Reno School of Medicine, Reno, Nevada and Co-Primary Investigator for the DIAMOND study, commented: *"If successful, OCS-01 will be an important therapeutic option in the treatment of patients with DME. As the first topical eye drop and non-invasive treatment for DME, OCS-01 can potentially benefit patients diagnosed with DME across the world to attain quicker and easier access to treatment. This may result in significantly reducing the burden to health care systems and improving patient outcomes."*

OCS-01 has been shown to improve visual acuity and reduce central macular thickness in DME patients compared to vehicle and demonstrated a promising safety profile in the 144-patient Phase 2b (DX-211) trial. The Phase 2 data were first presented at the Angiogenesis, Exudation, and Degeneration 2020 Conference in February 2020 and have since been published in the Acta Ophthalmologica journal in June 2022.

-ENDS-

About Oculis

Oculis is a global biopharmaceutical company purposefully driven to save sight and improve eye care. Oculis's highly differentiated pipeline consists of innovative candidates in development which include a topical retinal treatment for diabetic macular edema (DME), a topical biologic for dry eye disease (DED) and a disease modifying treatment for neuro-retina diseases such as acute optic neuritis (AON), glaucoma, geographic atrophy, and diabetic retinopathy. Headquartered in Switzerland and with operations in the U.S., China, and Europe, Oculis's 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

About Diabetic Macular Edema (DME)

DME affects 7% of people with diabetes[1], representing one in 14 people, and is the leading cause of visual loss and legal blindness in patients with diabetes. Based on the diabetes prevalence, it is estimated that DME currently affects around 37 million people worldwide and, as the prevalence of diabetes increases, it is estimated that the number of people affected will increase to 53 million by 2040[2]. DME is an irreversible and progressive complication of diabetic retinopathy and is related to consistently high blood sugar levels that damage nerves and blood vessels in the macula, the area of the retina responsible for sharp vision. DME occurs when blood vessels in the retina swell, and then leak, leading to a fluid build-up (edema) into the retina. There remains a significant need for safer, more effective, longer lasting and less burdensome treatments for DME patients.

(1) Yau et al. Global Prevalence and Major Risk Factors of Diabetic Retinopathy, Diabetes Care 2012 Mar; 35(3): 556-564.
(2) International Diabetes Federation – diabetesatlas.org Estimated diabetes prevalence worldwidein 2021: 537m, reaching 783m in 2045

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