Oculis Accelerates Enrollment in both DIAMOND Phase 3 Trials of OCS-01 in Diabetic Macular Edema and Expands its DIAMOND Program Committees

Oct 21, 2024

- *Phase 3 DIAMOND-1 and DIAMOND-2 trials enrollment of OCS-01 in diabetic macular edema (DME) accelerated with great momentum*
- *DIAMOND program committees expanded with globally renowned retina experts*
- *If approved, OCS-01 has the potential to transform the treatment paradigm as the first topical eye drop to treat DME.*

ZUG, Switzerland, October 21, 2024 – Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announces the acceleration of patient enrollment for both Phase 3 DIAMOND trials of OCS-01 eye drops in DME and expansion of the DIAMOND program committees with globally renowned retina experts.

Substantial enrollment progress was achieved since the end of Q2 2024 through early October, with ~70% of patients enrolled in the Phase 3 DIAMOND-1 trial, and ~40% of patients enrolled in the Phase 3 DIAMOND-2 trial. The DIAMOND (DIAbetic Macular edema patients ON a Drop) program consists of two (2) Phase 3, double-masked, randomized, multi-center trials which will evaluate the efficacy and safety of OCS-01 eye drops in patients with DME.

Arshad M. Khanani, M.D., M.A, FASRS, DIAMOND Program Steering Committee Chairperson, Oculis Board of Directors member, Scientific Advisory Board Chair of Retina and Director of Clinical Research at Sierra Eye Associates, commented: "I am honored to chair the DIAMOND steering committee, comprised of leading experts from around the globe, as we support the outstanding team at Oculis in the late-stage development of OCS-01. The results from Stage 1 of the DIAMOND Phase 3 program are promising, showing that patients treated with OCS-01 experienced significant improvements in visual acuity and a clinically meaningful reduction in macular edema. The DIAMOND program offers hope to the millions worldwide affected by DME, with OCS-01 potentially emerging as the first non-invasive topical eye drop therapy."

Riad Sherif, M.D., Chief Executive Officer of Oculis, said: "We are very pleased with the strong momentum in patient enrollment in DIAMOND-1 and DIAMOND-2 Phase 3 trials which continues to exceed our expectations. We are also honored to have such a distinguished and broad group of global experts on the expanded DIAMOND program committees and look forward to working with the committees and benefiting from their deep expertise as we advance the DIAMOND program."

The DIAMOND program committees are comprised of world-renowned experts who provide strategic oversight as Oculis develops OCS-01 which has the potential to be the first topical eye drop to transform DME treatment paradigm:

- **Arshad Khanani, M.D.**
- **David Almeida, M.D.**
- **Mark Barakat, M.D.**
- **Kirk Bateman, M.Sc.**
- **David Boyer, M.D.**
- **Margaret Chang, M.D.**
- **Saradha Chexal, M.D.**
- **Carl Danzig, M.D.**
- **Dilsher Dhoot, M.D.**
- **Diana Do, M.D.**
- **Frank Holz, M.D.**
- **Baruch D. Kuppermann, M.D.**
- **Timothy Lai, M.D.**
- **Anat Loewenstein, M.D.**
- **Sabri Markabi, M.D.**
- **Patricio Schlottmann, M.D.**
- **Ashish Sharma, M.D.**
- **Veeral Sheth, M.D.**
- **Michael Singer, M.D.**
- **Thomas Wolfensberger, M.D.**

For more information about the DIAMOND program committee members, please visit oculis.com.
To learn more about the Phase 3 DIAMOND trials, please visit diamondtrial.com.

About OCS-01 eye drops and the OPTIREACH® technology

Leveraging Oculis' proprietary technology, OCS-01 is an OPTIREACH ® formulation of high concentration dexamethasone eye drop. It was developed to treat the retina via an eye drop, a route of administration for DME that contrasts with currently available therapies, all requiring invasive delivery to reach the retina such as intravitreal injections or ocular implants. 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 the drug passage from the eye surface to the posterior segment of the eye. Oculis' OCS-01 is developed with the aim to transform the current treatment paradigm in DME as a non-invasive topical treatment option.

OCS-01 is an investigational drug that has not received regulatory approval for commercial use in any country.

About the Phase 3 DIAMOND Program of OCS-01 in Diabetic Macular Edema

The DIAMOND-1 (DIAbetic Macular edema patients ON a Drop) and DIAMOND-2 trials are Phase 3, double-masked, randomized, multi-center trials which will evaluate the efficacy and safety of OCS-01 eye drops in patients with DME. Oculis aims to enroll 350 patients in each of these pivotal trials that will be randomized 1:1 to receive OCS-01 or vehicle six times daily for the 6-week induction phase and then three times daily through week 52 for the maintenance phase. The primary endpoint is change in best corrected visual acuity early treatment diabetic retinopathy study (BCVA ETDRS) letter score at Week 52. Secondary endpoints include percentage of patients with ≥15-letter gain in BCVA and change in central subfield thickness (CST), both at Week 52. Both trials were initiated upon the positive findings from stage 1 of the DIAMOND program, which was announced in the second quarter of 2023, and both trials are currently enrolling.

About Diabetic Macular Edema (DME)

DME is the leading cause of visual loss and legal blindness in patients with diabetes. Currently, it is estimated to affect around 37 million people worldwide and, with the rise of diabetes, the prevalence is expected to increase to 53 million by 2040[1,2]. DME is an irreversible and progressive complication of diabetic retinopathy and is related to consistently having 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.

About Oculis
Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: 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; licaminlimab (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 neuroprotective candidate for acute optic neuritis (AON). Headquartered in Switzerland and with operations in the U.S. and Iceland, Oculis' goal is to improve the health and quality of life of 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: oculis.com

(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 worldwide in 2021: 537m, reaching 783m in 2045

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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 become the first non-invasive eye drop therapy for DME; the potential of OCS-01 to treat both front and back of the eye indications; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical trials, including the progress of Oculis' DIAMOND Phase 3 program with OCS-01 in DME; Oculis' research and development programs, regulatory and business strategy, future development plans, and management; and Oculis' ability to advance product candidates into, and successfully complete, clinical trials, 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.