Oculis' DIAMOND Phase 3 Program in Diabetic Macular Edema to be Presented at Innovate Retina and Eyecelerator 2024

Oct 15, 2024

ZUG, Switzerland, October 15, 2024 – Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced that an update on the DIAMOND Phase 3 program with OCS-01, an OPTIREACH® formulation of high concentration dexamethasone eye drop, for diabetic macular edema (DME) will be presented by David Eichenbaum, M.D. at Innovate Retina. In addition, Riad Sherif, M.D., Oculis' Chief Executive Officer, will be presenting at Eyecelerator 2024, ahead of the American Academy of Ophthalmology Annual Meeting where Oculis will be exhibiting (booth 5452).

Both presentations from Dr. Eichenbaum and Dr. Sherif will highlight the robust results with OCS-01 eye drops in DME from Stage 1 of the DIAMOND program at Week 12 and will present the design of Stage 2 to assess the efficacy and safety of OCS-01 eye drops for the treatment of DME at Week 52. Both Phase 3 trials (DIAMOND-1 and DIAMOND-2) are ongoing and aim to enroll 350 patients each.

Furthermore, Dr. Sherif's presentation will highlight upcoming near-term milestones, including the topline results from the ACUITY Phase 2 trial with OCS-05 for the treatment of acute optic neuritis, anticipated before the end of 2024.

Eyecelerator 2024
Format: Corporate presentation
Session: Retina Showcase
Presenter: Riad Sherif, MD, Chief Executive Officer
Presentation date and time: October 17, 2024 at 2:06 pm CT
Location: McCormik Place, Chicago, IL

Innovate Retina
Presentation title: OCS-01: novel topical approach for macular edema
Session: New Routes and New Molecules
Presenter: David Eichenbaum, MD
Presentation date and time: October 17, 2024 at 5:31 pm CT
Location: InterContinental Chicago Magnificent Mile, Chicago, IL

David Eichenbaum, M.D. is a board-certified ophthalmologist, fellowship-trained in diseases and surgery of the vitreous and retina and he is a Partner and Director of Research at Retina Vitreous Associates of Florida. Dr. Eichenbaum has served as Principal Investigator in over 90 Phase 1 though Phase 4 clinical trials and has published over 70 articles in professional journals, published multiple textbook chapters and regularly presents his work in scientific congresses. He also serves on numerous Clinical and Scientific Advisory Boards and National Executive Steering Committees for both commercial and pipeline products. Dr. Eichenbaum completed the Medical Honors Program at the University of South Florida, earning his undergraduate and medical degree in Tampa. He completed his Ophthalmology residency at the University of South Florida, where he served as Chief Resident, and completed his two-year Surgical Retina fellowship at Tufts New England Eye Center and Ophthalmic Consultants of Boston.

About Innovate Retina

Innovate Retina focuses exclusively on game-changing innovations in medical and surgical retina care, including current management of age-related macular degeneration (AMD) and diabetic retinopathy, ocular imaging, gene therapy, ocular inflammation, surgical technologies, ocular oncology, and the latest advances in retinal pharmacotherapy.

For more information, please visit: https://retinainnovate.com/

About Eyecelerator

Eyecelerator conferences provide a full day of KOL-driven programs highlighting industry advancements, investment trends, and innovative new products disrupting eye care. In partnership with the American Academy of Ophthalmology and the American Society for Cataract and Refractive Surgery, the event is held twice per year.

For more information, please visit: https://www.eyecelerator.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.

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 20401,2. 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 OCS-05

OCS-05 is a serum-glucose corticoid kinase-2 (SGK-2) activator with the potential to become a neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases. In ophthalmology, this mechanism of action could potentially protect the nerve axons in conditions such as acute optic neuritis, to ultimately prevent vision loss. In animal models of neuroinflammation and neurodegeneration, OCS-05 has shown positive results in prevention of retinal ganglion cell damage and was associated with improvements in clinical function (disability). The Phase 2 ACUITY study in Acute Optic Neuritis (AON) is currently ongoing with results anticipated before the end of the year.

OCS-05 is an investigational drug and has not received regulatory approval for commercial use in any country.

About Phase 2 ACUITY Trial

The Phase 2 ACUITY is an ongoing randomized, double-blind, multi-center, two-arm, placebo-controlled study to evaluate the safety and tolerability of once daily OCS-05 intravenous infusion in patients with Acute Optic Neuritis (AON).

Positive outcomes in this trial could support the development of the compound for potential application in the treatment of ophthalmic conditions where neuroprotection is needed.

About Acute Optic Neuritis

AON is a rare disease characterized by an acute inflammation of the optic nerve that can lead to permanent visual impairment. It affects up to 5 in 100,000 people worldwide each year and often represents the first sign of multiple sclerosis. It mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1). The acute inflammatory process of AON leads to the loss of myelin covering the optic nerve and the axons. At the onset, patients often suffer from ocular pain that increases with eye movement and vision loss. Once the inflammation recedes, remyelination often occurs but it is incomplete. Without the myelin sheath protecting the axon, neurons located in demyelinated segments become fragile and prone to death. Unfortunately, damaged axons cannot regrow, leading to permanent visual impairment.

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: www.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 and OCS-05, including patient impact and market opportunity; the potential of OCS-01 to become the first topical eye drop and non-invasive treatment option for DME; the potential of OCS-01 to treat both front and back of the eye indications; the potential of OCS-05 to become a neuroprotective therapy for AON and other neuro-ophthalmic diseases; the potential of OCS-05 to prevent vision loss; 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 and the progress of Oculis' Phase 2 ACUITY study in AON; anticipated clinical readouts, including the anticipated topline results for the Phase 2 ACUITY study in AON; 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.