Oculis Announces First Patient First Visit in Phase 3 DIAMOND-1 Trial of OCS-01 Eye Drop in Diabetic Macular Edema

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- *DIAMOND-1 Phase 3 trial, assessing the efficacy and safety of OCS-01 eye drops following 52 weeks of treatment in Diabetic Macular Edema (DME) patients, was initiated as planned*
- *Stage 1 results showed superiority of OCS-01 eye drops vs. vehicle with robust statistical significance with no unexpected adverse events observed*
- *Second 52 weeks Phase 3 trial of OCS-01 in DME, DIAMOND-2, is anticipated to start in Q1 2024*
- *If approved, OCS-01 has the potential to become the first topical eye drop and non-invasive treatment option for DME*

ZUG, Switzerland, and BOSTON, Dec. 18, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, announces First Patient First Visit (FPFV) in Stage 2 of its Phase 3 DIAMOND-1 trial evaluating Oculis' lead product candidate OCS-01 for the treatment of DME, a leading cause of preventable blindness in working-age adults affecting approximately 37 million people worldwide.

DIAMOND-1 (DIAbetic Macular edema patients ON a Drop) is a Phase 3, two-stage, double-masked, randomized, multi-center trial to assess the efficacy and safety of OCS-01 eye drops in DME patients. The primary objective of the 3-month Stage 1 was to select the optimal dosing regimen (n=148). OCS-01 achieved the primary endpoint with robust statistical significance showing improvement in Best Corrected Visual Acuity (BCVA) vs. vehicle at Week 6 following the induction phase (OCS-01: 7.2 letters vs. vehicle: 3.1 letters, p=0.007). The effect was sustained to Week 12 with the maintenance dose. Furthermore, 27.4% of patients in the OCS-01 group achieved ≥15-letter improvement in BCVA from baseline vs. 7.5% in the vehicle group at Week 12 (p=0.009). A statistically significant decrease in Central Subfield Thickness (CST) was also observed. In Stage 1, OCS-01 was well-tolerated with no unexpected adverse events observed. For more information about Stage 1 results, please click here.

Stage 2 of the trial aims to enroll 350-400 patients who will be randomized 1:1 to receive OCS-01 or vehicle six times daily for a 6-week induction phase and then three times daily for a subsequent 46-week maintenance phase. The endpoints for Stage 2 will be the same as in Stage 1 and evaluated at Week 52.

Riad Sherif, M.D., Chief Executive Officer of Oculis, remarked*:* "2023 has been a remarkable year for us with the achievement of multiple key milestones and timely execution of our development plans. A few weeks ago, we announced the initiation of the RELIEF Phase 2b Trial with OCS-02 in Dry Eye Disease and have now reached another key development milestone with the initiation of the Stage 2 of the Phase 3 DIAMOND-1 trial with OCS-01 in DME. OCS-01 is a promising clinical candidate that has already demonstrated its potential to treat both front and back of the eye indications with the positive results from Stage 1 of the DIAMOND trial in DME and the Phase 3 OPTIMIZE trial in inflammation and pain following cataract surgery. If approved, OCS-01 could become the first eye drop for DME and potentially transform the current treatment paradigm."

Arshad M. Khanani, M.D., M.A., FASRS, Co-Principal Investigator for the DIAMOND trial; Oculis Scientific Advisory Board member; Director of Clinical Research at Sierra Eye Associates and Clinical Associate Professor at University of Nevada, Reno School of Medicine, commented: "The treatment of DME with repeated intravitreal injections results in a significant burden for our patients. As a field, we have been actively seeking non-invasive alternatives to address DME, aiming to intervene earlier and alleviate treatment burden. OCS-01 eye drops have emerged as a potential solution for this unmet need, and the encouraging results from Stage 1 of the DIAMOND-1 Phase 3 trial support this outlook. The initiation of Stage 2 of the DIAMOND-1 study marks a crucial advancement in the development of OCS-01, positioning it as a promising non-invasive treatment option for patients with DME."

About OCS-01 eye drops and the OPTIREACH® technology

Leveraging Oculis' proprietary OPTIREACH ® technology, OCS-01 is a novel, high concentration (15 mg/ml), topical formulation of dexamethasone. It was developed to reach the retina via an eye drop, a route of administration for DME that contrasts with currently available therapies, all requiring invasive delivery to the retina such as ocular implants or intravitreal injections. 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.

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) 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; 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 disease modifying candidate for acute optic neuritis (AON) and other neuro-ophthalmic 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

(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 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; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical trials; 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.

Source: Oculis Holding AG