Positive Results from Phase 3 OPTIMIZE-1 Trial of Once Daily OCS-01 for the Treatment of Inflammation and Pain Following Cataract Surgery Presented at the 2024 American Society of Cataract and Refractive Surgery Annual Meeting

Apr 8, 2024

- *OCS-01 positive results in the first Phase 3 OPTIMIZE-1 trial were presented at the American Society of Cataract and Refractive Surgery (ASCRS) while topline readout from the second Phase 3 OPTIMIZE-2 is anticipated later this year to support NDA submission*
- *If approved, OCS-01 would be the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery*
- *OCS-01 is also in Phase 3 development as potentially the first eye drop treatment for Diabetic Macular Edema (DME)*

ZUG, Switzerland and BOSTON, April 08, 2024 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced that Eric Donnenfeld, M.D., presented the positive results from the Phase 3 OPTIMIZE-1 trial of OCS-01 for the treatment of inflammation and pain following cataract surgery at the 2024 ASCRS Annual Meeting, which took place April 5-8, 2024, in Boston, MA.

Dr. Donnenfeld presented the "Once Daily OCS-01, an OPTIREACH ® Formulation of High Concentration Dexamethasone Eye Drop, for Inflammation and Pain Following Cataract Surgery – a Phase 3, Double-Masked, Vehicle-Controlled Study" on Sunday, April 7 th. The results showed that 57.2% of patients treated with OCS-01 were inflammation free (i.e. absence of anterior chamber cells) at Day 15 (vs. 24.0% with vehicle, p<0.0001), and 75.5% had absence of ocular pain at Day 4 (vs. 52.0% with vehicle, p<0.0001).

Eric Donnenfeld, M.D., Clinical Professor of Ophthalmology at New York University and Co-chair of the Oculis Scientific Advisory Board, said: "The results from OPTIMIZE-1 were highly compelling, showing statistically significant impact on treating inflammation and pain following cataract surgery. Current treatment regimens require multiple daily doses of different eye drops, and having an effective once daily highly potent and safe anti-inflammatory eye drop with a good tolerability profile would meaningfully reduce the burden for patients, caregivers, and ultimately, improve surgery outcomes. OCS-01 is truly a unique product candidate with two specific advantages over conventional eye drops: a highly concentrated formulation with 15 times the concentration of available and approved dexamethasone eye drops and an improved solubility profile to enhance eye tissue penetration. These specific characteristics could explain the impressive results in DME in which OCS-01 eye drops significantly improved visual acuity and reduced macular edema."

Riad Sherif, M.D., Chief Executive Officer of Oculis, added: "We are excited that Dr. Donnenfeld shared the results from the OPTIMIZE-1 Phase 3 trial of OCS-01 at the ASCRS conference. The development program of OCS-01, a novel eye drop in development for both front-and-back-of-the-eye diseases, is progressing as planned with three ongoing Phase 3 trials: the second Phase 3 OPTIMIZE-2 trial, and the two ongoing 52-week DIAMOND-1 and DIAMOND-2 Phase 3 trials in DME. We look forward to sharing further milestone achievements of our pipeline including the upcoming topline clinical readouts with our differentiated assets as the year progresses."

Oculis initiated the second Phase 3 OPTIMIZE-2 trial with OCS-01 once daily eye drop in late 2023 and topline readout is expected before the end of 2024. The two Phase 3 OPTIMIZE trials are expected to support an NDA submission.

For more information about ASCRS 2024 visit: https://annualmeeting.ascrs.org/.

About inflammation and pain following ocular surgery

Ophthalmic surgeries are on the rise, mainly due to the aging population and lifestyle changes, and are expected to reach close to 10 million procedures per year in the U.S. alone by 2037[1,2]. Cataract surgeries are the most prevalent procedures of all medical specialties with an estimated 5 million procedures in 2021 in the US[2]. Ophthalmic surgeries cause the release of inflammatory factors and can be associated with ocular pain. Cataract surgery, even with a very small incision, creates inflammation in the cornea, anterior chamber, and iris. Ophthalmologists currently rely on topical steroids to treat ocular inflammation and the full regimen following ocular surgery often includes steroids, antibiotics and NSAID, which can have a different dosing regimen and require several drops daily for a post-op patient to administer, all leading to potential compliance issues.

About OCS-01 eye drops and the OPTIREACH® technology

Leveraging Oculis' proprietary OPTIREACH ® technology, OCS-01 is a novel, high concentration dexamethasone eye drop. 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 less frequent administration for front-of-the-eye and the drug passage from the eye surface to the posterior segment for back-of-the-eye diseases.

[1] 2016 HCUP procedure volume and growth rate, and corroborated by Rochester Epidemiology Project Paper. Third party market research.

[2] Meddevicetracker – Ophthalmic Surgical Products Market 2017.

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 U.S., 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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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 for treating front- and back-of-the-eye diseases; the potential for OCS-01 to become a new standard of care with the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery; the potential of OCS-01 for the treatment of DME, inflammation and pain following ocular surgery and CME; expected future milestones and catalysts; expected topline clinical readouts, including the expected topline readout from OPTIMIZE-2; the initiation, timing, progress and results of Oculis' clinical and preclinical studies; Oculis' research and development programs, regulatory and business strategy, future development plans, and management; Oculis' ability to advance product candidates into, and successfully complete, clinical trials; and the timing or likelihood of regulatory filings and approvals, 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.