Oculis Announces First Patient First Visit in Phase 2b RELIEF Trial of Topical Anti-TNFα Licaminlimab (OCS-02) in Dry Eye Disease

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- *Licaminlimab is a novel anti-TNFα biologic eye drop with an established dual mechanism of action, anti-inflammatory and anti-apoptotic, and a potential transformative impact on the treatment of inflammatory eye diseases*
- *RELIEF Phase 2b trial will evaluate the efficacy and safety of licaminlimab in moderate-to-severe Dry Eye Disease, and further explore the potential of a genetic biomarker*
- *Trial was initiated as planned with topline results expected in mid-2024*

ZUG, Switzerland and BOSTON, Dec. 07, 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 its Phase 2b RELIEF trial evaluating the potential of licaminlimab (also known as OCS-02), Oculis' innovative anti-TNFα biologic eye drop, for the treatment of Dry Eye Disease (DED).

The Phase 2b RELIEF trial is a multi-center, randomized, double-masked, vehicle-controlled trial evaluating the safety and efficacy of licaminlimab for the treatment of signs and symptoms in moderate- to-severe DED. Furthermore, the trial will evaluate if patients with a specific genetic biomarker identified in a prior trial respond better to licaminlimab. The trial was designed after several trials with licaminlimab in DED and Uveitis demonstrated positive findings. 120 patients are planned to be randomized to either licaminlimab or vehicle for a 6-week treatment and a 2-week follow up period. Topline results are anticipated in mid-2024.

Riad Sherif, M.D., Chief Executive Officer of Oculis, remarked*:* "We are very pleased to have achieved First Patient First Visit (FPFV) in the RELIEF trial as planned. The initiation of this trial represents a key milestone as we advance the development of OCS-02, a promising, differentiated candidate in Dry Eye. This achievement builds on our earlier successes this year with positive Phase 3 results from our other lead asset, OCS-01, in diabetic macular edema and post ocular surgery. DED remains an area of unmet medical need with only 13% of patients achieving lasting relief after 12 months of treatment in a large and growing market affecting approximately 40 million patients in the U.S. We are confident that licaminlimab, given its proven mechanism of action and its prior clinical trials results, will have transformative potential in DED. We look forward to sharing the topline results in mid-2024."

Eric Donnenfeld, M.D., Clinical Professor of Ophthalmology at New York University and Co-chair of Oculis Scientific Advisory Board, said: "Licaminlimab is a promising topical candidate, which has already shown strong data in two prior trials with over 215 patients, where it demonstrated superiority over vehicle in alleviating ocular discomfort in patients with severe DED while also being well tolerated. Another unique finding from a prior Phase 2a trial was the discovery of a genetic biomarker that may help identify high responders to licaminlimab, which we look forward to exploring in the RELIEF trial."

Christophe Baudouin, M.D., Professor of Ophthalmology and Chairman of Ophthalmology III at Quinze-vingts National Ophthalmology Hospital, Paris, and member of Oculis Scientific Advisory Board, commented: "Patients with DED, especially in its severe form, experience considerable impact on their quality of life due to the significant pain and discomfort it causes, among other signs and symptoms. Unfortunately, currently available treatments only provide lasting relief for a small portion of the patient population, and as a result, new treatment approaches are needed. Licaminlimab leverages the already proven mechanism of action (MOA) of anti-TNFα which could be very beneficial given the central role of ocular surface inflammation in DED. In fact, it's been shown that tears from DED patients contain increased concentrations of inflammatory cytokines, such as TNFα, that are correlated to disease severity. I believe that the anti-inflammatory and anti-apoptotic effects of blocking TNFα could potentially revolutionize the treatment of several inflammatory eye conditions, similarly to what anti-TNFα treatments have shown in other therapeutic areas."

About Dry Eye Disease

DED is a common condition estimated to impact nearly 40 million people in 2023 in the US alone[1]. It is known as a multifactorial disease in which ocular surface inflammation plays a central role in sustaining the pathological state[2,3]. It usually affects both eyes and patients may experience a stinging, burning or scratchy sensation. In addition, some patients experience sensitivity to light, eye redness, difficulty wearing contact lenses, difficulty with nighttime driving, and blurred vision which can greatly affect their quality of life.

Of the approximately 20 million patients who are diagnosed with DED in the U.S., about half or 10 million are considered to have moderate to severe disease; however, only 9% receive prescription treatment, primarily with an anti-inflammatory medications[1]. Despite currently available treatments, only 13% of chronic patients said that they experienced lasting relief[4] highlighting the tremendous unmet need remaining in this underserved patient population. Furthermore, given the heterogenicity of the DED patient population, there is a need for more personalized treatment approaches, to improve outcomes for 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 retinal candidate for diabetic macular edema (DME); OCS-02, a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED); 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

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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 licaminlimab or OCS-02 in the treatment of inflammatory eye diseases or DED, the potential of a genetic biomarker; 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.

[1] DRG (part of Clarivate) – Dry Eye Disease Landscape and Forecast report 2020

[2] TFOS DEWS II The Ocular Surface 15 (2017)

[3] Baudouin C. Dry Eye Disease, the complex interactions of vicious cycles. EuDES European Dry Eye Society https://www.dryeye-society.com/resources/dry-eye-disease-complex-interactions-vicious-cycles

[4] Mukamal, R. Why is Dry Eye So Difficult to Treat? 2021 https://www.aao.org/eye-health/tips-prevention/fix-dry-eye-treatment-eyedrops

Source: Oculis Holding AG