Oculis announces publication of Phase 2 data showing topical eye drops anti-TNFα agent licaminlimab (OCS-02) relieves persistent ocular discomfort in severe dry eye disease

- ***Positive Phase 2 data, published in Clinical Ophthalmology, highlights the potential of licaminlimab to become a novel treatment in DED***
- ***Primary and secondary efficacy endpoints were successfully met and showed superiority of licaminlimab over vehicle for the relief of ocular discomfort in patients with severe DED***
- ***Licaminlimab was well tolerated, with no increase in intra-ocular pressure and no other safety issues identified***

LAUSANNE, Switzerland, August 23, 2022 – Oculis S.A., ('Oculis') a global ophthalmology company developing life-changing treatments to save sight and improve eye care with breakthrough innovations, announces that the results of the double blinded, multicenter and placebo controlled Phase 2 clinical trial assessing the effect of topical licaminlimab (OCS-02) on global ocular discomfort in patients with severe dry eye disease (DED) (NCT02365519) has been published by the Clinical Ophthalmology journal. The publication is accessible on the National Institutes of Health (NIH) website here.

The results from the study show that the change from baseline to Day 29 in the global ocular discomfort score, the primary efficacy endpoint, was statistically significantly greater for topical ocular licaminlimab (OCS-02) (-7.9) than for vehicle (-3.6) (90% CI -7.7, -0.8; p = 0.041). The percentage of patients with an improvement in global ocular discomfort score >20 from baseline to treatment day 29, one of the main secondary efficacy endpoints, was statistically greater for licaminlimab (17.9%) compared to vehicle (4.7%) (p=0.018).

Licaminlimab (OCS-02) was well tolerated in this study, with no major safety differences between licaminlimab (OCS-02) and vehicle treatment groups, and no increase in intra-ocular pressure was observed.

Licaminlimab (OCS-02) is a single-chain antibody fragment (scFv) that binds to and neutralizes the activity of human TNFα, with dual mechanism of action (MoA), anti-inflammation and anti-necrosis. Unlike full-length monoclonal antibodies, scFv fragments can penetrate ocular surface tissues when used as eye drops, due to the smaller size of the molecule giving it the potential to become the first approved topical biologic for DED.

Dry Eye is a multifactorial disease in which inflammation rapidly takes on a central role in sustaining the pathological state[1]. The global prevalence of DED has been reported at 11.59%[2], representing approximately 900 million people worldwide. In the US alone, there is currently between 16 million and 49 million people who

[1] Baudoin C. Dry Eye Disease, the complex interactions of vicious cycles. EuDESEuropean Dry Eye Society https://www.dryeye-society.com/resources/dry-eye-disease-complex-interactions-vicious-cycles

[2] Eric B Papas "The global prevalence of dry eye disease: A Bayesian view" 2021

have dry eye disease[3]. Significant unmet medical needs remain for this large and growing patient population with only 9% of diagnosed patients in the US receiving treatment[4] and despite current options, only 13% of patients are achieving lasting relief[5].

Licaminlimab (OCS-02) is currently being investigated by Oculis in Phase 2 clinical trials for the treatment of dry eye disease and uveitis.

Pr Christophe Baudouin, M.D., Professor of Ophthalmology and Chairman of Ophthalmology III in Quinze-vingts National Ophthalmology Hospital, Paris, commented*: "There is a true unmet medical need for the development of drugs with new MOA to treat the inflammation involved in the pathogenesis of DED. OCS-02 is certainly one that could fill that gap. As compared to currently available treatment options and other product candidates in the DED pipeline, OCS-02 could play a role in the treatment of the underlying causes of the disease given its anti-inflammatory and anti-necrosis benefits. I certainly look forward to the continued development and approval of OCS-02 in severe dry eye disease as these patients currently have limited treatment options."*

Riad Sherif, M.D., CEO of Oculis, said: *"The Phase 2 data further reinforce our confidence in the potential of OCS-02 as a novel anti-inflammatory treatment for the effective management of Dry Eye Disease, but also for other inflammatory eye diseases. With Phase 2b clinical trials of OCS-02 for the treatment of dry eye disease and uveitis which are planned to start in the coming months, along with on-going Phase 3 clinical trials of OCS-01 in diabetic macular edema and inflammation and pain following ocular surgery and a proof-of-concept (POC) trial of OCS-05 in acute optic neuritis, we look forward with confidence to the further development of the Oculis Ophthalmology Franchise to address significant unmet medical needs in key areas of ophthalmology."*

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About Oculis

Oculis is a global biopharmaceutical company purposefully driven to save sight, improve eye care and address significant unmet medical needs with breakthrough innovations. Oculis's highly differentiated pipeline includescandidates for topical retinal treatments, topical biologics and disease modifying treatments. With a presence in key international markets, Oculis is poised to deliver life-changing treatments to patients worldwide. Headquartered in Lausanne, Switzerland and with operations in Europe, the U.S. and China, Oculis is led by an experienced management team with a successful track record and supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

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[3] https://dryeyedirectory.com/dry-eye-statistics/

[4] DRG Dry Eye Disease Landscape and Forecast 2020

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

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