



Oculis announces publication of positive Phase 2 data in *Translational Vision Science & Technology (TVST)* investigating topical anti-TNF α agent Licaminlimab (OCS-02) in acute anterior uveitis

- ***Positive data show topical anti-TNF α agent Licaminlimab eye drops reduced inflammation in Acute Anterior Uveitis (AAU), meeting the study's primary efficacy endpoint***
- ***Peer-reviewed paper highlights potential of Licaminlimab to become a novel non-steroidal topical treatment in anterior uveitis***
- ***Topical administration of Licaminlimab was well-tolerated with no significant ocular or non-ocular safety findings***

LAUSANNE, Switzerland, November 22, 2022 – Oculis S.A., (Oculis) a global ophthalmology company developing life-changing treatments to save sight and improve eye care, announces that the results of its Licaminlimab active-controlled, multicenter, randomized, parallel-group Phase 2 clinical trial assessing the effect of topical Licaminlimab (OCS-02) on anterior chamber (AC) cell grade in patients with acute anterior uveitis (AAU) (NCT02482129) has been published in *Translational Vision Science & Technology (TVST)*, an ARVO journal. The study, "Topical Ocular Anti-TNF α Agent Licaminlimab in the Treatment of Acute Anterior Uveitis: A Randomized Phase II Pilot Study", is accessible on the National Institutes of Health (NIH) website [here](#).

The study met its primary objective according to prospectively specified criteria, in the treatment of patients with AAU, and thereby established evidence of treatment effect. The data showed a response rate on Day 15 of 56% for Licaminlimab-treated patients, defined as a reduction from baseline in AC cell grade of ≥ 2 (SUN). Secondary and exploratory endpoints in the study were also supportive of the treatment effect of Licaminlimab (OCS-02) eye drops, with most patients demonstrating a reduction of ≥ 2 units from baseline in AC cell grade by day eight, with few patients requiring rescue therapy, most patients achieving an AC cell grade of zero in at least one visit, and the median change from baseline in AC cell grade being equivalent to responder status. Licaminlimab (OCS-02) was observed to be well tolerated, including no increase in intra-ocular pressure (IOP) related to Licaminlimab (OCS-02).

Uveitis is a general term describing a group of inflammatory diseases that produces swelling and destroys eye tissues. These diseases can slightly reduce vision or lead to severe vision loss. In the United States alone, there are more than 300,000 Americans suffering from non-infectious uveitis. Anterior uveitis is the most prevalent type accounting for 85% of this patient population and about half of the cases are considered to be either recurring or chronic. Corticosteroids are the current mainstay of therapy, usually administered topically, although peri-ocular or systemic treatment may be used, depending on the extent and severity of disease. Corticosteroid therapy, whether topical, periocular, or systemic, can lead to increased IOP, which increases the risk of glaucoma, and cataracts.

Licaminlimab (OCS-02) is an anti-TNF α antibody product candidate based on an innovative antibody fragment technology allowing it to be administered topically. Its dual mechanism of action (MoA), anti-inflammation and anti-necrosis, is clinically proven with other anti-TNF α antibodies already approved as systemic treatment for ocular diseases and with transformative impact in other therapeutic areas. If approved, Licaminlimab (OCS-02) has the potential to become the first topical anti-TNF α to be approved for treatment of non-infectious anterior uveitis, and could help address the significant medical need for a steroid-sparing agent and for a topical biologic to be indicated specifically for non-infectious anterior uveitis without the associated systemic risks.

Phase 2b clinical trials of Licaminlimab (OCS-02) for the treatment of non-infectious anterior uveitis, as well as Dry Eye Disease (DED), are currently being planned by Oculis.

Anat Galor, M.D., Professor of Ophthalmology at the University of Miami Health System, said: *“There is a clear medical need for non-steroidal anti-inflammatory therapies for uveitis. This is particularly important for patients who require longer-term anti-inflammatory treatment given that long-term steroid treatment is not optimal due to the associated side effect profile. The positive results recently published demonstrate the potential of OCS-02 as a topical, non-steroidal therapy for non-infectious anterior uveitis and have been crucial to inform the planned clinical trials for OCS-02 as a steroid-sparing treatment for patients with recurring or chronic anterior uveitis, where its unique profile may offer the greatest benefit to patients.”*

Riad Sherif, M.D., CEO of Oculis, said: *“These positive data further strengthen the potential of Licaminlimab, if approved, to become the first topical biologic to treat anterior uveitis, which could provide patients and physicians around the globe with a non-steroidal option, an area of high medical need. Oculis is currently planning the start of two phase 2b studies in 2023, to further assess the potential of this novel product candidate in chronic anterior uveitis but also, in DED, another inflammatory condition, where we believe it also has tremendous potential to provide a new option to doctors to treat their patients.”*

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About

Oculis is a global biopharmaceutical company purposefully driven to save sight and improve eye care. Oculis's highly differentiated pipeline consists of innovative candidates in development which include a topical retinal treatment for diabetic macular edema (DME), a topical biologic for dry eye disease (DED) and a disease modifying treatment for neuro-retina diseases such as acute optic neuritis (AON), glaucoma, geographic atrophy, and diabetic retinopathy. Headquartered in Switzerland and with operations in the U.S., China, and Europe, Oculis's 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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