



Next Generation Topical Ophthalmics

## Oculis Announces Positive Data from Two Proof-of-Concept Phase 2 Trials with OCS-02, a Novel Topical TNF alpha Antagonist, in Dry Eye Disease and Acute Anterior Uveitis, Presented at ARVO 2021

- **Positive Phase 2a data, presented for the first time, highlights the potential of OCS-02 to become a new treatment in moderate to severe DED and potentially the first personalized therapy in this disease**
- **Data also highlight the opportunity for OCS-02 to become a novel non-steroidal anti-inflammatory treatment for Anterior Uveitis.**

**LAUSANNE, Switzerland, May 11<sup>th</sup>, 2021** – Oculis S.A., ('Oculis') a late-stage biopharmaceutical company focused on developing transformative ophthalmic treatments to improve the sight and lives of patients, today announces positive data from two clinical proof of concept Phase 2 trials with OCS-02, its novel, topical anti-TNF alpha antibody fragment candidate, in Dry Eye Disease (DED) and Acute Anterior Uveitis (AAU). The data were presented for the first time at ARVO 2021, the annual meeting of the Association for Research in Vision and Ophthalmology, which took place virtually from May 1-7, 2021.

**Riad Sherif, M.D. Chief Executive Officer of Oculis said:** "We are very excited to present these data for the first time at ARVO 2021. The data from these two Phase 2 trials highlight the potential of OCS-02 in key indications that affect the anterior segment of the eye and have serious implications for the sight and well-being of patients. The progression of OCS-02 clinical development further strengthens our pipeline."

**Marcia de Souza Lima, M.D., Chief Medical Officer of Oculis, added:** OCS-02 is a promising product candidate as it combines the proven anti-inflammatory effects and safety of anti-TNF alpha biologics, as seen with currently approved systemic treatments, with the convenience of topical delivery."

### For OCS-02 in Dry Eye Disease

- Abstract # 3543422
- Title: Variant in the TNFR1 gene associated with response to topical anti-TNF $\alpha$  antibody fragment OCS-02 in patients with dry eye disease
- Authors: Victor L. Perez, M.D., on behalf of the OCS-02 DED PoC Phase 2 study group
- Clinicaltrial.gov identifier code: NCT02365519 (OCS-02 was previously known as LME636)
- A video recording of the presentation can be found in the Pipeline section of [www.oculis.com](http://www.oculis.com)

In the Phase 2, multicenter, randomized, vehicle-controlled, double masked, prospective study, OCS-02 was found to be significantly more effective than vehicle in relieving severe ocular discomfort associated with DED ( $p=0.041$ ). A pre-specified exploratory pharmacogenetics analysis demonstrated a statistically significant association between response to OCS-02 in patients with DED and a genetic biomarker ( $p<0.0001$ ). Additional studies are needed to better understand the role of unique gene variants in DED and susceptibility to anti-TNF $\alpha$  therapies. The aim of the next clinical study will be to validate the role of OCS-02 as a new anti-inflammatory treatment for DED and the biomarker, which could enable OCS-02 to become the first personalized treatment in this indication.

**Victor L. Perez, M.D., Stephen and Frances Foster Distinguished Professor of Ocular Immunology and Inflammation, Duke University School of Medicine, said:** "The results presented are very encouraging and we were intrigued to see a correlation between a genetic variant and improved response to OCS-02 treatment. I believe it could be very helpful in clinical practice to be able to predict response to treatment,

especially in dry eye given the heterogeneous population affected by this disease. If confirmed in other clinical trials, this could become a novel and potentially highly impactful approach to treat DED in patients with the highest need.”

### **For OCS-02 in Uveitis**

- Abstract # 3522243
- Title: Efficacy and Safety of OCS-02 a novel, potent, topical TNF $\alpha$  antibody in acute anterior uveitis (AAU): a phase 2 study
- Authors: Anat Galor, MSPH, on behalf of the OCS-02 Acute Anterior Uveitis Phase 2 study group
- Clinicaltrial.gov identifier code: NCT02482129 (OCS-02 was previously known as LME636)
- A video recording of the presentation can be found in the Pipeline section of [www.ocularis.com](http://www.ocularis.com)

In this Phase 2, multicenter, randomized, parallel-group, double-masked, active-controlled study of patients with Acute Anterior Uveitis, the administration of OCS-02 demonstrated efficacy, in accordance with the prespecified criteria, in resolving ocular inflammation. OCS-02 was well tolerated without steroid-type side effects or eye irritation.

**Anat Galor, M.D., Professor of Ophthalmology at the University of Miami Health System, said:** “There is a clear unmet 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 presented at ARVO 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.”

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### **About Ocularis**

Headquartered in Lausanne, Switzerland with global operations in Europe and the U.S., Ocularis is a biopharmaceutical company focused on developing transformative innovative ophthalmic treatments to improve the sight and lives of patients. Ocularis has a robust and expansive development portfolio including late-stage novel topical (eye drop) treatments, which are non-invasive and represent an unprecedented technical advance for patients with retinal edema and front-of-the-eye diseases. In addition, Ocularis’ formulation discovery focus and capabilities enable the development of a pipeline of topical drugs targeting sight-threatening eye diseases that affect both the anterior and posterior segments of the eye.

To learn more, please visit [www.ocularis.com](http://www.ocularis.com)

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