Oculis Completes Randomization in PREDICT-1 Registrational Trial of Licaminlimab for TNFR1-Mediated Dry Eye Disease

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High-Responder Target Enrichment: 2/3 of the 176 enrolled patients carry the target TNFR1 genetic variant previously linked to enhanced clinical response in Phase 2 trials

Precision Medicine Approach in a Large Market: Licaminlimab is positioned as a potential first-in-class precision medicine for an estimated 1.5+ million patients in the U.S. with moderate-to-severe TNFR1-mediated dry eye disease (DED)[1-4], addressing a critical unmet need in a historically heterogeneous indication.

Key Milestone on Track: Topline data from this first-ever genotype-guided registrational trial in DED are anticipated around year-end 2026

ZUG, Switzerland, October 19, 2026 -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) (Oculis), a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology, today announced completion of randomization in the PREDICT-1 (**P**ersonalized d**R**y **E**ye **D**isease **I**nvestigational **C**linical **T**rial) genotype-based registrational trial of Licaminlimab to drive precision medicine in dry eye disease (DED). Oculis expects to report topline results around year-end 2026.

Riad Sherif, M.D., Chief Executive Officer of Oculis, said, *"Completing randomization in such a timeframe with a new modality demonstrates that genotype-driven development is crucial and precision medicine is urgently needed in DED. PREDICT-1 is an important operational milestone as we track toward topline results around year-end 2026. In prior Phase 2 studies, Licaminlimab showed robust improvement across both signs and symptoms of dry eye disease, with an amplified response in patients harboring a specific TNFR1 genotype. Importantly, a simple, non-invasive genetic biomarker test can identify this patient population, supporting the practical application of this precision medicine approach. PREDICT-1 builds directly on that scientific rationale to validate our genotype-guided strategy. If successful, Licaminlimab has the potential to pioneer a first-in-class precision medicine treatment paradigm, delivering targeted relief to a large, underserved patient population with TNFR1-driven disease."*

Anat Galor, M.D., M.S.P.H., Professor of Ophthalmology, Bascom Palmer Eye Institute, Miami, added: *"Dry eye disease is a highly heterogeneous condition, and treatment response can vary considerably between patients. As a result, selecting the right therapy often involves a lengthy trial-and-error process that can lead to patient dissatisfaction and early treatment discontinuation. A precision medicine approach to identify individuals more likely to benefit from a specific therapy could meaningfully advance care for both patients and clinicians. The findings observed in earlier studies of Licaminlimab provide a compelling rationale for the PREDICT-1 trial, and I look forward to seeing whether this targeted approach can advance a more effective treatment paradigm and improve outcomes for patients living with dry eye disease."*

PREDICT-1, the program's first registrational trial, is designed to evaluate the efficacy of Licaminlimab in DED symptoms compared with vehicle in patients carrying a specific TNFR1 genotype, while also assess its effect and safety in the overall study population. Randomization is complete, with 176 patients enrolled in this randomized, multicenter, double-masked, vehicle-controlled study, 2/3 of whom have the specified TNFR1 genotype. The primary endpoint is the change from baseline at Day 29 in the global ocular discomfort severity score in patients with the specified TNFR1 genotype. The same outcome measure will be evaluated in the overall study population as a key secondary endpoint. Oculis expects to report topline results around year-end 2026.

In a prior Phase 2 trial evaluating DED symptoms, patients treated with Licaminlimab experienced a statistically significant reduction in ocular discomfort compared with vehicle at Day 29, with a rapid onset of action observed as early as Day 14.[5]

TNFR1 is a receptor that mediates TNFα-driven inflammation and apoptosis. In phase 2 trials, Licaminlimab has shown greater clinical response, with substantial improvements in signs and symptoms, among patients with a specific TNFR1 genotype. These findings are consistent with the literature suggesting that genetic variation in the TNF/TNFR1 pathway may account for variability in the inflammatory response[6], and that TNFR1-mediated inflammation may play a key role in ocular surface pathology in DED. A simple biomarker test could identify the relevant genetic variant, potentially helping physicians determine which patients are more likely to benefit from treatment. The PREDICT-1 trial is designed to leverage these findings with the aim to deliver precision medicine to patients with TNFR1-mediated DED.

An estimated 40 million people in the U.S. have DED and about half are formally diagnosed.[1] Among them, approximately 10 million have moderate-to-severe disease requiring active treatment.[1-2] Current disease management relies heavily on a trial-and-error therapeutic approach, with only ~13% of patients achieving sustained relief[7], driving an 85–90% discontinuation rate within the first six months[8] and underscoring the urgent need for targeted, effective therapy. Approximately 13% to 19% of patients with moderate-to-severe DED, representing an estimated 1.3 to 1.9 million individuals, carry the relevant TNFR1 genetic variant and could potentially benefit from Licaminlimab.[1-4] If approved, Licaminlimab has the potential to transform the treatment landscape by shifting from today's trial-and-error approach to the first precision medicine for TNFR1-mediated DED.

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About Licaminlimab

Licaminlimab is an anti-TNFα eye drop candidate being developed with a single chain antibody fragment (scFv) technology specifically developed to treat ocular inflammatory diseases. The dual anti-inflammatory and anti-necrotic mechanism of action of TNF-α inhibition has been well-established in inflammatory disorders where the systemic use of TNF-α inhibitors has led to marked improvements in the disease management and treatment outcomes. In Phase 2 trials, Licaminlimab has shown a positive treatment effect on both the signs and symptoms of DED and has been well tolerated. In addition, a genetic biomarker has been identified which showed a more pronounced treatment effect with Licaminlimab in patients with a specific TNFR1 genotype. If approved, Licaminlimab has the potential to transform the treatment paradigm with a precision medicine approach.

Licaminlimab is an investigational drug in registrational trial and has not received regulatory approval for commercial use in any country.

About Dry Eye Disease (DED)

DED is a multifactorial disease in which ocular surface inflammation plays a central role in sustaining the pathological state[9,10]. 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.

It is a common condition estimated to impact more than 110 million people in the G7 countries (U.S., U.K., Germany, France, Spain, Italy, Japan).[1] 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.[1,2] However, only 13% of DED patients receive prescription treatment, primarily with anti-inflammatory medications[1] and despite available therapies, most patients (87%) don't feel that their chronic DED is well-managed [7] which highlights a high level of dissatisfaction. Furthermore, 90% of patients discontinued their treatment altogether within one year with the vast majority discontinuing in the first 6 months.[8] Unmet medical needs remain for novel anti-inflammatory treatments which are efficacious, fast-acting and well-tolerated as well as developing targeted therapeutics for specific patient subtypes to improve treatment outcomes for this heterogeneous patient population.

About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology. Oculis' highly differentiated late-stage clinical pipeline focuses on two core product candidates. Privosegtor is a breakthrough neuroprotective candidate in the PIONEER program, which consists of studies intended to support registration plans for treatment of optic neuropathies, including optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION). Privosegtor also has potential to be developed for additional indications in other neuro-ophthalmic and neuro-axonal diseases. Licaminlimab is a novel, topical anti-TNFα in a registrational trial, and is being developed with a genotype-based approach for treating patients with dry eye disease (DED). Headquartered in Switzerland with operations in the U.S., Iceland and Switzerland, 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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Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the potential benefits of the Company's product candidates, including the potential of Licaminlimab to redefine the treatment paradigm in dry eye disease with a precision medicine approach and satisfy an unmet medical need; the initiation, timing, progress and results of current and future clinical trials, including the progress and timing of the PREDICT-1 trial of Licaminlimab and timing of topline results; Oculis' research and development programs, regulatory and business strategy; expected milestones; and statements about market opportunity and the estimated number of DED patients with the specific TNFR1 genotype, 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. Results from prior clinical trials may not be replicated in later clinical trials. 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 exhibit to Oculis' Form 6-K filed on August 6, 2026 and any other documents filed with 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.

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