Oculis Announces First Patient Randomized in PREDICT-1 Registrational Trial of Licaminlimab, Advancing Precision Medicine in Dry Eye Disease

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- *PREDICT-1 is the first genotype-based registrational trial in dry eye disease (DED), with the potential of delivering a first-in-class precision medicine treatment in DED*
- *This FDA-aligned trial targets the specific TNFR1 genotype to maximize treatment effects, with ~70% of clinical sites already activated and patients in the run-in phase*
- *With only 13% of DED patients experiencing sustained relief, Licaminlimab has the potential to offer a targeted precision solution for a highly unsatisfied market*

ZUG, Switzerland, June 09, 2026 (GLOBE NEWSWIRE) -- 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 announces that the first patient has been randomized in the PREDICT-1 (**P**ersonalized d**R**y **E**ye **D**isease **I**nvestigational **C**linical **T**rial) genotype-based registrational trial in dry eye disease (DED). If approved, Licaminlimab has the potential to transform the treatment paradigm for DED with a precision medicine approach.

The first registrational trial in the program, PREDICT-1, is designed to further evaluate the efficacy of Licaminlimab in DED symptoms and its safety compared with vehicle in patients carrying a specific TNFR1 genotype, while also evaluating the effect in the overall study population. The PREDICT-1 trial is a randomized, multi-center, double-masked, vehicle-controlled study that plans to enroll ~160 patients of whom approximately 2/3 will have the specified TNFR1 genotype. The primary endpoint is the change from baseline to 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. While measurements of dry eye symptoms are inherently subjective, this precision medicine approach is designed to identify patients more likely to benefit from Licaminlimab.

To maximize the efficiency of the registration study, PREDICT-1 incorporates a screening phase. This process is designed to ensure appropriate patient selection based on genotype status assessed prior to the artificial tear run-in phase, as well as ocular discomfort severity (≥60 in the global ocular discomfort severity score), evaluated both before and after the run-in phase.

TNFR1 is a key receptor mediating TNFα-driven inflammation and apoptosis. Licaminlimab has shown greater clinical response in patients with a specific TNFR1 genotype in Phase 2 trials, with substantial improvements in signs and symptoms. These findings are consistent with the literature suggesting that genetic variation in the TNF/TNFR1 pathway may account for variability in the inflammatory response[1], and that TNFR1-mediated inflammation may play a key role in ocular surface pathology in DED. The PREDICT-1 trial is designed to leverage these findings with the aim of delivering the first precision medicine treatment in ophthalmology.

In the U.S. approximately 10 million diagnosed patients suffer from moderate to severe DED.[2,3] Current disease management relies on a trial-and-error therapeutic approach, with a minority (~13%) of patients experiencing sustained relief,[4] leading to an 85-90% discontinuation rate within the first 6 months, underscoring the significant unmet need for a targeted, effective treatment approach.[5] If approved, Licaminlimab has the potential to transform the current DED treatment paradigm by providing a precision medicine approach with high efficacy, rapid onset of action, and a comfort level similar to artificial tears.

Riad Sherif, M.D., Chief Executive Officer of Oculis, remarked, "The first patient randomized in PREDICT-1 marks an important milestone for Licaminlimab and for the advancement of a genotype-based, precision medicine approach in dry eye disease, a highly unsatisfied market. Supported by a well-validated anti-TNFα mechanism of action, this targeted trial is designed to maximize clinical efficiency by focusing on patients most likely to respond. We believe Licaminlimab, if approved, has the potential to reshape the treatment paradigm for this multifactorial disease. By pioneering an innovative development strategy, our objective is to deliver a precision medicine approach that addresses a major unmet need for the millions of underserved patients currently constrained by a trial-and-error method."

Anat Galor, M.D., M.S.P.H., Professor of Ophthalmology, Bascom Palmer Eye Institute, Miami added: "The advancement of Licaminlimab represents a meaningful progress in dry eye disease research, particularly in light of the substantial unmet need among patients and clinicians, many of whom remain dissatisfied and frustrated with the current 'trial-and-error' treatment paradigm. Results from prior Phase 2 studies demonstrated clinically relevant improvements in both signs and symptoms, with a more pronounced and differentiated response observed in patients carrying a specific TNFR1 genotype. If confirmed in the PREDICT-1 study, this genotype-informed, precision medicine approach has the potential to enable a more targeted treatment strategy for this highly heterogeneous patient population, where a significant unmet medical need persists."

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 an five- to seven-fold more pronounced treatment effect with Licaminlimab in patients with a variant in the TNFR1 gene. If approved, Licaminlimab has the potential to transform the treatment paradigm of DED 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[6,7]. 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).[2] 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.[2,3] However, only 13% of DED patients receive prescription treatment, primarily with anti-inflammatory medications[2] and despite available therapies, most patients (87%) don't feel that their chronic DED is well-managed [4] 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.[5] 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 neurological 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 and mechanisms of action, including the potential for Licaminlimab to address unmet medical need and transform the treatment paradigm for DED with a precision medicine approach, the initiation, timing, progress and results of current and future clinical trials, Oculis' research and development programs, regulatory and business strategy; Oculis' future development plans; the timing or likelihood of regulatory filings and approvals; and statements about market opportunity, 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 (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.

References:

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