Oculis Announces Positive Topline Results of Phase 2b RELIEF Trial with Licaminlimab, Designed to Transform the Treatment Paradigm of Dry Eye Disease with a Precision Medicine Strategy

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ZUG, Switzerland, June 10, 2024 (GLOBE NEWSWIRE) --

- *Improvements in multiple sign efficacy endpoints were observed in full population and with predictive and more pronounced effects in the TNFR1 genetic biomarker population as identified in prior successful Phase 2 symptoms trial*
- *Rapid treatment effect on corneal inflammation was observed in TNFR1 genetic biomarker patients as early as Day 15 and was statistically significant at final efficacy visit on Day 43*
- *Licaminlimab was well tolerated similar to vehicle*
- *Company plans to finalize Phase 3 development plans following an End-of-Phase 2 (EoP2) meeting with the U.S. Food and Drug Administration (FDA)*
- *An investor and analyst webcast will be held today at 8:30am US Eastern Time*

Oculis Holding AG (Nasdaq: OCS) ("Oculis"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced positive topline results from its Phase 2b RELIEF trial with licaminlimab, a novel anti-TNFα biologic eye drop with an established dual anti-inflammatory and anti-apoptotic mechanism of action in patients with dry eye disease (DED).

The Phase 2b RELIEF trial is a multi-center, randomized, double-masked, vehicle-controlled trial evaluating the efficacy and safety of licaminlimab in subjects with signs of DED (NCT05896670). The trial also evaluated the efficacy and safety of licaminlimab in a subpopulation of subjects with a TNFR1-related genotype as prespecified in the protocol. One hundred and twenty-two (122) patients were randomized 1:1 to either licaminlimab (n=62) or vehicle (n=60) across 4 sites for a 6-week treatment period and a 2-week follow up. A total of 23 patients carried a specific TNFR1-related genotype. Patients were evaluated for efficacy endpoints at baseline, Day 15 and Day 43. The prespecified investigational efficacy measures in this trial included multiple signs of DED that are accepted by the FDA as efficacy endpoints.

Phase 2b RELIEF trial showed positive effects on multiple signs of DED

- For the full trial population (n=122):
  - Treatment effect favoring licaminlimab was observed in multiple sign endpoints including fluorescein staining in the total cornea, inferior corneal, central corneal and nasal conjunctival regions, and in the Schirmer's test.
- For the subpopulation of patients with the TNFR1 genetic biomarker (n=23):
  - Treatment effect favoring licaminlimab was observed in multiple sign endpoints including fluorescein staining in the total cornea, inferior corneal, central corneal, nasal conjunctival, total conjunctival and total ocular surface regions, in the Schirmer's test, and in conjunctival redness.
  - Rapid and favorable treatment effect in favor of licaminlimab on corneal inflammation was observed as early as Day 15 that was significant at Day 43, as measured by the difference in mean change from baseline versus vehicle for inferior corneal fluorescein staining score: -0.59 (CI: -1.165, -0.017). The treatment effect also increased over time. See attached Figure.
  - Licaminlimab was well tolerated. The incidence of ocular TEAEs in the study eye was 11.5% in the licaminlimab group and 10.2% in the vehicle group. TEAEs in the fellow eye were similar to the study eye. All ocular TEAEs were mild and transient, and there were no serious ocular adverse events observed with licaminlimab in the study. Drop comfort was also evaluated and was similar to artificial tears.

Riad Sherif, MD, Chief Executive Officer of Oculis, commented: "We are pleased that we achieved all of our objectives for the trial, and extremely encouraged to see licaminlimab's profound results with a precision medicine approach which has the potential to transform the way we develop drugs and treat patients in ophthalmology. With this and prior positive results on signs and symptoms, we look forward to discussing these encouraging data with the FDA and advancing this program into Phase 3."

Eric Donnenfeld, M.D., Clinical Professor of Ophthalmology at New York University and Chair of Oculis' Cornea Scientific Advisory Board, added: "The precision medicine approach with licaminlimab could be a groundbreaking paradigm shift in ophthalmology and the treatment of DED. The current approach of 'trial and error' and our inability to predict response for this highly heterogenous population leads to a low level of patient satisfaction. To my knowledge, Licaminlimab is the first dry eye disease medication to demonstrate in a clinical trial a predictive treatment effect in patients with a common genetic biomarker to potentially solve this problem."

Christophe Baudouin, M.D., Ph.D., Professor of Ophthalmology and Chairman of Ophthalmology III at Quinze-vingts National

Ophthalmology Hospital, Paris, and member of Oculis Scientific Advisory Board, added: "I am very excited to see that licaminlimab, with its dual anti-inflammatory and anti-apoptotic mechanism of action, targets the origin of DED and has the potential to be truly disease modifying as shown by improvements in several clinical signs of DED, including corneal staining."

The Company is planning to conduct an end-of-Phase 2 meeting with the FDA to discuss the registrational path for licaminlimab in DED and finalize the Phase 3 development plan.

Analyst and investor call
The Oculis management team will host an analyst and investor call today at 8:30 am US Eastern Time, to review the trial results.

Interested parties may participate in the call via the following webcast here.

A replay of the webcast and accompanying slides will be available for 90 days following the event through the "Events and Presentations" page of the "Investors and Media" section of the company's website.

About Dry Eye Disease (DED)
DED is a common condition estimated to impact nearly 40 million people in 2023 in the US alone[1]. It is a multifactorial disease in which ocular surface inflammation plays a central role in sustaining the pathological state[2,3]. 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.

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]. However, only 13% receive prescription treatment, primarily with an anti-inflammatory medications[1]. Despite currently available treatments, with 87% of chronic patients still unsatisfied[4] highlighting the tremendous unmet need remaining in this underserved patient population. Furthermore, given the heterogenicity of the DED patient population, there is a need for more personalized treatment approaches to improve outcomes for patients.

About licaminlimab (OCS-02)
Licaminlimab is an anti-TNFα eye drop candidate developed with a single chain antibody fragment (scFv) technology specifically designed 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 multiple Phase 2 trials, licaminlimab has shown positive effects on treating both the signs and symptoms of DED and has been well tolerated. In addition, a genetic biomarker was identified which showed a clear correlation between this variant in the TNFR1 gene and improved response to licaminlimab.

Licaminlimab is an investigational drug and has not received regulatory approval for commercial use in any country. For more information, please visit: www.oculis.com

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About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) purposefully driven to save sight and improve eye care. Oculis' highly differentiated pipeline comprises multiple innovative product candidates in development. It includes OCS-01, a topical eye drop candidate for diabetic macular edema (DME) and for the treatment of inflammation and pain following cataract surgery; licaminlimab (OCS-02), a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED) and for non-infectious anterior uveitis; and OCS-05, a neuroprotective candidate for acute optic neuritis (AON). Headquartered in Switzerland and with operations in the U.S. and Iceland, Oculis' goal is to improve the health and quality of life of patients worldwide. The company is led by an experienced management team with a successful track record and is supported by leading international healthcare investors.

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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 licaminlimab, including patient impact and market opportunity; the potential of licaminlimab for treating DED; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical and preclinical studies; Oculis' research and development programs, regulatory and business strategy, future development plans, and management; Oculis' ability to advance product candidates into, and successfully complete, clinical trials; and the timing or likelihood of regulatory filings and approvals, are forward-looking. The clinical trial results presented in this press release are topline and preliminary and subject to change, as analysis is ongoing. These topline results may not be reproduced in subsequent patients and clinical trials. 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 (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.

[1] DRG (part of Clarivate) – Dry Eye Disease Landscape and Forecast report 2020
[2] TFOS DEWS II The Ocular Surface 15 (2017)

[3] Baudouin C. Dry Eye Disease, the complex interactions of vicious cycles. EuDES European Dry Eye Society https://www.dryeye-society.com/resources/dry-eye-disease-complex-interactions-vicious-cycles

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

Attachment

- Figure 1 - RELIEF Topline Results PR