Oculis Announces Completion of Enrollment in Phase 2 Randomized Controlled ACUITY Trial with OCS-05 for Acute Optic Neuritis

May 8, 2024

- *Topline results anticipated in Q4 2024 for Phase 2 trial evaluating the safety and tolerability of OCS-05 in patients with Acute Optic Neuritis (AON)*
- *Oculis also aims to complete an IND submission for OCS-05 in the U.S. in 2024*
- *OCS-05 has been granted orphan drug designation in the United States and Europe for AON, an indication for which there are no approved therapies*

ZUG, Switzerland, May 08, 2024 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS; XICE: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced the completion of enrollment in its multi-center, randomized, double-blind, placebo-controlled Phase 2 ACUITY trial evaluating the safety and tolerability of OCS-05 in patients with Acute Optic Neuritis (AON). Topline results are expected in Q4 2024.

The Phase 2 ACUITY study is evaluating once-daily OCS-05 intravenous infusion in patients with AON. The study is ongoing across four (4) sites in France.

At present, there are no approved therapies for AON, leaving a significant gap in medical care for treatments that offer neuroprotection and can prevent vision loss. OCS-05 has been granted orphan drug designation in both the United States and Europe, highlighting the importance of this unmet medical need.

Riad Sherif, M.D., Chief Executive Officer of Oculis, commented*:* "We continue to execute on our strategic programs and are pleased to complete enrollment in the ACUITY trial, an important milestone for OCS-05 clinical program that keeps us on track for an anticipated topline readout in Q4 this year. In the meantime, we keep on working towards an IND submission for OCS-05 in the U.S. in 2024. We anticipate that a positive readout in this trial would support further development of OCS-05 as a potential first-in-class neuroprotective treatment with wide applicability in neuro-ophthalmic diseases such as AON, glaucoma, geographic atrophy, diabetic retinopathy and other diseases where protecting retinal neurons is key to preserving patients' sight."

Sophie Bonnin M.D., Ph.D., Deputy Head of the Ophthalmology Department, at Rothschild Foundation Hospital, in Paris, and Scientific Advisor for the ACUITY trial, said: "AON is a rare disease characterized by acute inflammation and demyelination of the optic nerve. While corticosteroids are used to shorten the attack, there is no approved therapy for AON and unmet needs remain for therapies that can prevent vision loss after an acute episode of optic neuritis. The completed enrollment brings us a step forward in the development of OCS-05 as a potential neuroprotective candidate which could have a profound impact in ophthalmology, and we are eagerly awaiting the anticipated trial readout in Q4 of this year."

Pablo Villoslada M.D., Chair, Department of Neurology, Hospital del Mar, Barcelona, and Oculis Scientific Advisory Board member, said: "The completion of enrollment in the ACUITY trial in patients with an acute inflammatory-demyelinating disorder is very exciting. The novel and differentiated mechanism of action of OCS-05 triggers multiple beneficial effects on apoptosis, oxidation and inflammation which supports neuronal survival and repair. The results from this Phase 2 trial will provide an opportunity to further understand this mechanism of action in a clinical setting and explore its potential benefits for patients suffering from ophthalmic diseases where neuroprotection is needed."

About OCS-05

OCS-05 is a serum-glucose corticoid kinase-2 (SGK-2) activator with the potential to become a neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases. In ophthalmology, this mechanism of action could potentially protect the nerve axons in conditions such as acute optic neuritis, to ultimately prevent vision loss. In animal models of neuroinflammation and neurodegeneration, OCS-05 has shown positive results in prevention of retinal ganglion cell damage and was associated with improvements in clinical function (disability). The Phase 2 ACUITY study in Acute Optic Neuritis (AON) is currently ongoing with results anticipated before the end of the year.

OCS-05 is an investigational drug and has not received regulatory approval for commercial use in any country.

About Phase 2 ACUITY Trial

The Phase 2 ACUITY is an ongoing randomized, double-blind, multi-center, two-arm, placebo-controlled study to evaluate the safety and tolerability of once daily OCS-05 intravenous infusion in patients with Acute Optic Neuritis (AON).

Positive outcomes in this trial could support the development of the compound for potential application in the treatment of ophthalmic conditions where neuroprotection is needed.

About Acute Optic Neuritis

AON is a rare disease characterized by an acute inflammation of the optic nerve that can lead to permanent visual impairment. It affects up to 5 in 100,000 people worldwide each year and often represents the first sign of multiple sclerosis. It mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1). The acute inflammatory process of AON leads to the loss of myelin covering the optic nerve and the axons. At the onset, patients often suffer from ocular pain that increases with eye movement and vision loss. Once the inflammation recedes, remyelination often occurs but it is incomplete. Without the myelin sheath protecting the axon, neurons located in demyelinated segments become fragile and prone to death. Unfortunately, damaged axons cannot regrow, leading to permanent visual impairment.

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; 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.

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 OCS-05, including patient impact and market opportunity; the potential of OCS-05 to become a disease-modifying, neuroprotective therapy for AON, glaucoma and other neuro-ophthalmic diseases; the potential of OCS-05 to prevent vision loss; expected future milestones and catalysts; anticipated clinical readouts, including the anticipated topline results for the Phase 2 ACUITY study in AON; 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; the timing or likelihood of regulatory filings and approvals; and the timing or likelihood of Oculis' IND submission for OCS-05 in the U.S., 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 (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.