Oculis to Host In-Person and Virtual R&D Day on Key Business Updates and the Development Plans for Privosegtor (OCS-05) in Acute Optic Neuritis and Beyond

Apr 1, 2025

ZUG, Switzerland, April 01, 2025 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) (“Oculis” or the “Company"), a global biopharmaceutical company focused on innovations addressing ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs, today announced that it will host an in-person and virtual R&D Day on Tuesday, April 15, 2025 from 10:00 AM to 12:00PM ET at the Intercontinental New York Barclay hotel. To register for the event, **click here.**

The event will provide an update on Oculis’ portfolio of innovative late-stage clinical candidates, highlight recent clinical data and next steps, as well as discuss future development programs and business strategy. It will feature world-renowned key opinion leaders (KOLs):

Retina:

- **David Boyer, MD** (Keck School of Medicine, University of Southern California, and Retina Vitreous Associates Medical Group)
- **Arshad Khanani, MD, MA, FASRS** (Reno School of Medicine, University of Nevada, and Sierra Eye Associates);
- **Baruch D. Kuppermann, MD, PhD** (Department of Ophthalmology, University of California, Irvine and Gavin Herbert Eye Institute)
- **Sebastian Wolf, MD, PhD** (Department of Ophthalmology, University of Bern);

Inflammation and precision medicine:

- **Anat Galor, MD, MSPH** (Bascom Palmer Eye Institute, Miller School of Medicine, University of Miami);

Neuro-ophthalmology:

- **Mark Kupersmith, MD** (Departments of Ophthalmology and Neuroscience, Mount Sinai);
- **Leonard Levin, MD, PhD** (Departments of Ophthalmology & Visual Sciences and Neurology & Neurosurgery, McGill University);
- **Pablo Villoslada, MD, PhD** (Department of Neurology, Hospital del Mar, Pompeu Fabra University and Department of Neuroscience, Stanford University);

The presentations will include an update on progress with both Phase 3 DIAMOND trials of OCS-01 eye drops in diabetic macular edema (DME), Licaminlimab (OCS-02)’s development plan with precision medicine in dry eye disease (DED) and an expanded data analysis from the ACUITY Phase 2 trial as well as the development plans for Privosegtor (OCS-05) in acute optic neuritis and beyond.

The event will also outline Oculis’ portfolio strategy to drive pipeline value and maximize resource deployment.

A live question and answer session will follow the formal presentations.

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About OCS-01 eye drops and the OPTIREACH® technology
Leveraging Oculis’ proprietary technology, OCS-01 is an OPTIREACH ® formulation of high concentration dexamethasone eye drop. It is being developed as an eye drop to treat the retina to offer a non-invasive treatment alternative for diabetic macular edema (DME). This route of administration enables easy access to treatment in the early stages of the disease and can be used in combination with other therapies in later stages. In contrast, all currently available treatments require invasive delivery methods, such as intravitreal injections or ocular implants, to reach the retina. The OPTIREACH® solubilizing formulation technology addresses the main limitations of conventional eye drops by improving the solubility of lipophilic drugs, increasing the residence time on the eye surface and thereby, enabling the drug passage from the eye surface to the posterior segment of the eye. Oculis’ OCS-01 is being developed with the aim to transform the current treatment paradigm in DME as a non-invasive topical treatment option.

OCS-01 is an investigational drug in Phase 3 that has not received regulatory approval for commercial use in any country.

About Diabetic Macular Edema (DME)
DME is the leading cause of visual loss and legal blindness in patients with diabetes. Currently, it is estimated to affect around 37 million people worldwide and, with the rise of diabetes, the prevalence is expected to increase to 53 million by 2040[1,2]. DME is an irreversible and progressive complication of diabetic retinopathy and is related to consistently having high blood sugar levels that damage nerves and blood vessels in the macula, the area of the retina responsible for sharp vision. DME occurs when blood vessels in the retina swell, and then leak, leading to a fluid build-up (edema) into the retina. There remains a significant need for safe, efficacious, and less burdensome treatments for DME patients.

About Licaminlimab (OCS-02)
Licaminlimab is an anti-TNFα eye drop candidate being 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 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 improved response to Licaminlimab in patients with a variant in the TNFR1 gene.

Licaminlimab is an investigational drug in Phase 2 and has not received regulatory approval for commercial use in any country.

About Dry Eye Disease (DED)
DED 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)

and 40 million people in the U.S. alone[3]. It is a multifactorial disease in which ocular surface inflammation plays a central role in sustaining the pathological state[4,5]. 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[3]. However, only 13% receive prescription treatment, primarily with an anti-inflammatory medications[3]. Despite currently available treatments, 87% of chronic patients still unsatisfied[6] 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 personalized treatment approaches to improve outcomes for patients.

About Privosegtor (OCS-05)
Privosegtor is a novel peptidomimetic small molecule candidate with the potential to become a first-in-class neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases. The recent positive topline results in the ACUITY Phase 2 trial showed Privosegtor (OCS-05)'s neuroprotective benefits in anatomical preservation of the retina and visual function improvements in patients suffering from acute optic neuritis. Consistent results were observed in animal models of neuroinflammation and neurodegeneration where Privosegtor showed preservation of retinal ganglion cell damage and was associated with improvements in mobility (clinical function disability). Privosegtor has received orphan drug designation from both the FDA and the EMA for acute optic neuritis. In addition to this indication, a neuroprotective treatment could potentially have wide applicability in neuro-ophthalmic and neurology indications.

Privosegtor is an investigational drug in Phase 2 and has not received regulatory approval for commercial use in any country.

About Acute Optic Neuritis
Acute optic neuritis is a rare condition characterized by an acute inflammation of the optic nerve that can lead to permanent visual impairment. It affects up to 8 in 100,000 people worldwide and often represents the first sign of multiple sclerosis[7]. It mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1)[8]. The acute inflammatory process of acute optic neuritis 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. To date there is no specific neuroprotective therapy approved for acute optic neuritis and unmet needs remain for therapies that can prevent vision loss after an acute episode of optic neuritis.

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 of multiple innovative product candidates in clinical development includes: OCS-01, a topical eye drop candidate for diabetic macular edema (DME); Privosegtor (OCS-05), a neuroprotective candidate for acute optic neuritis with potentially broad clinical applications in other neuro-ophthalmic diseases; and Licaminlimab (OCS-02), a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED). Headquartered in Switzerland with operations in the U.S. and Iceland, Oculis 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-01, Licaminlimab (OCS-02), and Privosegtor (OCS-05), including patient impact and market opportunity; the potential of OCS-01 to transform the current treatment paradigm in DME as a non-invasive topical treatment option; the potential of Licaminlimab (OCS-02) to treat ocular inflammatory diseases; the potential of Privosegtor (OCS-05) to become a first-in-class neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases; the potential of Privosegtor (OCS-05) to potentially have wide applicability in neuro-ophthalmic and neurology indications; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical trials, including the progress with both Phase 3 DIAMOND trials of OCS-01 eye drops in DME; Oculis' research and development programs, regulatory and business strategy, future development plans, including Licaminlimab (OCS-02)'s development plan with precision medicine in DED, and development plans for Privosegtor (OCS-05) in acute optic neuritis and beyond; and management, 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 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. Yau et al. Global Prevalence and Major Risk Factors of Diabetic Retinopathy, Diabetes Care 2012 Mar; 35(3): 556-564
2. International Diabetes Federation – diabetesatlas.org Estimated diabetes prevalence worldwide in 2021: 537m, reaching 783m in 2045

3. DRG (part of Clarivate) – Dry Eye Disease Landscape and Forecast report 2020
4. TFOS DEWS II The Ocular Surface 15 (2017)
5. 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
6. Mukamal, R. Why is Dry Eye So Difficult to Treat? 2021 https://www.aao.org/eye-health/tips-prevention/fix-dry-eye-treatment-eyedrops
7. Martínez-Lapiscina EH, et al. (2014): Is the incidence of optic neuritis rising? Evidence from an epidemiological study in Barcelona (Spain) 2008-2012. *J Neurol*. 2014 Apr; 261(4): 759-767.
8. Pérez-Cambrodí RJ, Gómez-Hurtado Cubillana A, Merino-Suárez ML, Piñero-Llorens DP, Laria-Ochaita C. Optic neuritis in pediatric population: a review in current tendencies of diagnosis and management. J Optom. 2014 Jul-Sep;7(3):125-30.