Oculis Announces Presentation of Phase 2 ACUITY trial results with Privosegtor in Acute Optic Neuritis at ECTRIMS

Sep 22, 2025

- Privosegtor ACUITY Trial showed Improved LCVA and preservation of Ganglion Cells in Acute Optic Neuritis. Results from a Multicenter Randomized Placebo-Controlled Double-Masked Trial

ZUG, Switzerland, Sept. 22, 2025 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) ("Oculis"), a global biopharmaceutical company focused on innovations for ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs, today announced the upcoming presentation of the positive Phase 2 ACUITY trial results investigating Privosegtor (OCS-05) in acute optic neuritis at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 2025 Congress.

Details of Oculis' presentation:

ECTRIMS 2025:

- *Reduction in Retinal Ganglion Cell Loss and Improved Low Contrast Visual Acuity with Privosegtor in Acute Optic Neuritis: Results from a Multicenter Randomized Placebo-Controlled Double-Masked Trial.*
  Presenter: Céline Louapre, M.D., Ph.D., Pitié-Salpêtrière Hospital
  Session: Late Breaking Abstracts
  Date/Time: Thursday, September 25, 2025; 16:30 CET

Riad Sherif, M.D., Chief Executive Officer of Oculis, commented: "It is a privilege to collaborate with Pitié-Salpêtrière Hospital, a world-renowned center for modern neurology, on the Phase 2 ACUITY trial investigating Privosegtor (OCS-05) in patients with acute optic neuritis, a well-established clinical model for neuroprotection. Topline results showed clinically meaningful improvements in vision with 18 letters at 3 months, along with the preservation of retinal structure and a favorable safety profile, highlighting Privosegtor's potential broad applicability in various neuro-ophthalmic and neurological diseases. We look forward to sharing these significant results with the multiple sclerosis community as we continue to advance this candidate into further studies in optic neuritis and beyond, including a new program to be initiated for the treatment of MS relapses."

Céline Louapre, M.D., Ph.D., added: "It is an honor to present these positive results at ECTRIMS, the largest MS congress in the world. In this study, Privosegtor (OCS-05) demonstrated promising neuroprotective effects, including the preservation of retinal ganglion cells, and was also associated with significant improvements in low contrast visual acuity. With acute optic neuritis often manifesting as the first sign of multiple sclerosis or as a frequent MS relapse type, these results highlight the potential of this neuroprotective candidate to transform outcomes for patients experiencing acute relapses of this autoimmune disease."

Céline Louapre, M.D., Ph.D., is the Head of Neuroscience Clinical Investigation Center at the Paris Brain Institute, Pitié-Salpêtrière Hospital, where more than 80 clinical trials are currently conducted in the field of neuroscience. As a clinical neurologist with a Ph.D. in neuroscience, she is particularly interested in bringing new MRI technical developments to study the pathophysiologic mechanisms of MS, and in developing translational clinical research to foster remyelination and neuroprotection. She also serves as the Medical Coordinator of the National Multiple Sclerosis Clinical Research Network, FCRIN4MS, and as a Professor of Neurology at Sorbonne University, Pitié-Salpêtrière Hospital.

About Privosegtor (OCS-05)
Privosegtor is a novel peptoid small molecule candidate with the potential to become a neuroprotective therapy for optic neuritis and other neuro-ophthalmic diseases. The recent positive topline results from the ACUITY Phase 2 trial showed Privosegtor (OCS-05)'s neuroprotective benefits, including anatomical preservation of the retina and improvements in visual function, 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 acute inflammation of the optic nerve, which 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[1]. It mainly occurs in adults between the ages of 20 and 40 years and is more frequent in women (2:1)[2]. The acute inflammatory process of acute optic neuritis results in the loss of myelin covering the optic nerve and its axons. Initially, patients often experience ocular pain that worsens with eye movement, and vision loss. Once the inflammation recedes, remyelination usually occurs but it is incomplete. Without the myelin sheath protecting the axon, neurons located in demyelinated segments become fragile and prone to death, as early as the first weeks following symptoms onset. Unfortunately, damaged axons cannot regrow, leading to permanent visual impairment. To date there is no neuroprotective therapy approved for acute optic neuritis and unmet needs remain for medicines that can prevent vision loss after an acute episode of optic neuritis.

About Oculis
Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) focused on innovations addressing ophthalmic and neuro-ophthalmic conditions with significant unmet medical needs. Oculis' highly differentiated late-stage clinical pipeline includes three core product candidates: OCS-01, an eye drop in pivotal registration studies, aiming to become the first non-invasive topical treatment for diabetic macular edema; Privosegtor (OCS-05), a neuroprotective candidate in Phase 2 for acute optic neuritis, with potentially broad clinical applications in various neuro-ophthalmic and neurological diseases; and Licaminlimab (OCS-02), a novel, topical anti-TNFα in Phase 2, being developed with a genotype-based approach to drive personalized medicine in dry eye disease. 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 supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

(1) 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.

(2) 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.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the potential benefits of Privosegtor (OCS-05), including patient impact and market opportunity; the potential of Privosegtor (OCS-05) to become a first-in-class neuroprotective therapy for acute optic neuritis and other neuro-ophthalmic diseases; the initiation, timing, progress and results of Oculis' clinical trials; Oculis' research and development programs, regulatory and business strategy and future development plans; and Oculis' ability to advance product candidates into, and successfully complete, clinical trials, 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.

Oculis Contacts
Ms. Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Investor Relations
LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com

Media Relations
ICR Healthcare
Amber Fennell / David Daley / Sean Leous
oculis@icrhealthcare.com