Oculis Announces European Medicines Agency PRIME Designation for Privosegtor, Advancing a Potential First-in-Class Neuroprotective Candidate for Optic Neuritis

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- ***PRIME** designation follows recent Breakthrough Therapy designation from the U.S. FDA, underscoring the importance and urgency of addressing optic neuritis, a serious condition that can have negative long-term visual outcomes, significantly affecting function and quality of life*
- *Decision supported by positive Phase 2 ACUITY data showing substantial improvements in vision combined with anatomical and biological neuroprotective benefits in patients treated with Privosegtor*
- *Strong regulatory momentum bolsters the global development strategy, with PIONEER registrational program in optic neuropathies underway, potentially providing Privosegtor with an accelerated regulatory pathway*

ZUG, Switzerland, March 31, 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 ophthalmology and neuro-ophthalmology, today announced that its neuroprotective candidate Privosegtor has been granted **Pri**ority **Me**dicines (PRIME) designation by the European Medicines Agency (EMA) for the treatment of optic neuritis (ON), a rare, sight-threatening condition that is often a relapse of multiple sclerosis or its first clinical manifestation.

This decision follows the recent granting of Breakthrough Therapy designation for Privosegtor for the treatment of ON, by the U.S. Food and Drug Administration (FDA) announced in January 2026, reinforcing global regulatory support. The EMA grants PRIME designations to only a small, selective number of programs each year. They provide early and proactive support to developers of promising medicines that may offer a major therapeutic advantage over existing treatments or provide benefits to patients without treatment options. These medicines are considered priority medicines by the EMA, which aims to optimize development plans and expedite evaluations so that medicines addressing significant unmet medical needs can reach patients faster. Privosegtor also has Orphan Drug status from both the EMA and the FDA for ON.

Privosegtor, a novel peptoid small molecule that crosses both the blood–brain and retinal barriers, has the potential to become the first neuroprotective therapy for optic neuropathies. These serious conditions carry a significant unmet need, because they can lead to permanent visual impairments from nerve cell damage and death. There are no neuroprotective treatments currently available, and together, they represent a potential market opportunity of $7 billion in the U.S. alone.

The EMA's **PRIME** designation is supported by compelling visual-function results from the Phase 2 ACUITY trial in ON. In this trial, Privosegtor + steroid delivered substantial improvement in low-contrast visual acuity (LCVA), as well as consistent anatomical and biological benefits versus placebo + steroid, reinforcing its potential as a neuroprotective treatment across both neuro-ophthalmic and neurological diseases. Taken together with the ACUITY trial design, these results were determined by the EMA to be compatible with a magnitude of effect that has the potential to significantly address unmet need in ON treatment.

Following a successful meeting with the FDA in the fall of 2025, Oculis is now advancing the PIONEER program, which includes three global registrational trials in ON and a second rare neuro-ophthalmic disease, non-arteritic anterior ischemic optic neuropathy (NAION). The first registrational trial in the program, PIONEER-1 in ON, was initiated in Q4 2025, with clinical site activation progressing as planned.

Riad Sherif, M.D., Chief Executive Officer of Oculis, said: "EMA's decision to grant **PRIME designation** highlights Privosegtor's compelling results and its potential as a first-in-class neuroprotective therapy for people experiencing optic neuritis. Despite the current use of corticosteroids to shorten the inflammatory attack after an acute episode of optic neuritis, there remains an unmet medical need for novel therapies that can prevent vision loss by providing neuroprotection. Through our PIONEER registrational program, we look forward to further progressing Privosegtor's late-stage clinical development globally and delivering on our commitment to redefine what's possible for patients."

About Privosegtor

Privosegtor, a novel peptoid small-molecule candidate that crosses the blood-brain and retinal barriers, has the potential to become the first neuroprotective therapy for optic neuritis (ON) and other neuro-ophthalmic diseases. Positive results from the ACUITY Phase 2 trial demonstrated Privosegtor's neuroprotective potential through anatomical preservation of the retina and improvements in visual function after an acute episode of optic neuritis. Consistent results were observed in animal models of neuroinflammation and neurodegeneration, where Privosegtor preserved retinal ganglion cell damage and was associated with improvements in mobility (clinical function disability). Privosegtor has received Breakthrough Therapy designation from the FDA and Orphan Drug designation from both the FDA and the EMA for ON and is now entering registrational trials for this indication, as well as a registrational trial in non-arteritic anterior ischemic optic neuropathy (NAION), as part of Oculis' PIONEER (Privosegtor Investigation in Optic Neuropathies Efficacy Evaluation Research) program. In addition to its potential neuroprotective effect on the optic nerve, Privosegtor could also have wide applicability in treating other neuro-ophthalmic and neurological indications.

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

About Optic Neuritis

Optic Neuritis (ON) 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 with a U.S. annual incidence estimated to be >30,000 and often represents the first sign of multiple sclerosis[1,2]. It mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1)[3]. ON is a type of neuropathy (nerve disease) that happens when acute inflammation of the optic nerve affects the signals traveling from the eyes through the brain, causing pain, vision loss and other symptoms. The cells that make up the optic nerve have a lipid protective coating called a myelin sheath, which is preferentially damaged in ON. Without myelin, the optic nerve cells can't send signals properly and axons can be irreversibly lost. To date there is no specific therapy approved for acute optic neuritis and the unmet needs remain for therapies that can prevent vision loss after an acute episode by reducing nerve cell permanent damage or death.

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 includes three core product candidates: Privosegtor, a breakthrough neuroprotective candidate in the PIONEER program which consists of studies intended to support registration plans for treatment in optic neuropathies like optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION), with potentially broad clinical applications in various other neuro-ophthalmic and neurological diseases; OCS-01, an eye drop in pivotal registration studies, aiming to become the first non-invasive topical treatment for diabetic macular edema (DME); and Licaminlimab, a novel, topical anti-TNFα in registrational trial, which is being developed with a genotype-based approach to drive precision medicine in 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 supported by leading international healthcare investors.

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

About Priority Medicines designation

Priority Medicines (PRIME) designation is a scheme run by the European Medicines Agency (EMA) to enhance support for the development of medicines targeting unmet medical needs. The designation is awarded to medicines that show particular promise for patients with conditions where no treatment option exists, or where they can offer a major therapeutic advantage over existing treatments.

PRIME provides enhanced interaction and early dialogue between medicine developers and the EMA to optimize development plans and accelerate assessment. The scheme offers several key benefits, including early appointment of scientific coordinators, iterative scientific advice at major development milestones, expedited follow-up guidance with shortened timelines, and confirmation of potential accelerated assessment at the time of marketing authorization application.

Developers of medicines that benefit from PRIME can expect to be eligible for accelerated assessment at the time of application for marketing authorization, potentially expediting patient access to innovative therapies across the EU.

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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, the initiation, timing, progress and results of current and future clinical trials, Oculis' research and development programs, regulatory and business strategy; the potential of regulatory designations to accelerate the development of Privosegtor; the potential market opportunity for Oculis' product candidates; and Oculis' future development plans, 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 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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