Oculis Announces Positive FDA Pre-IND Feedback Supporting Privosegtor Development Strategy for Treatment of Acute Multiple Sclerosis Relapses

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- *The FDA Division of Neurology provided positive feedback supporting a regulatory pathway for Privosegtor in acute multiple sclerosis (MS) relapses, addressing a significant unmet medical need*
- *The FDA confirmed that existing Privosegtor data can be cross-referenced for a new Investigational New Drug (IND) application in acute MS relapses, planned for submission in the fourth quarter of 2026*
- *Privosegtor, a novel neuroprotective candidate, continues to advance across core neuro-ophthalmology indications, including optic neuropathies and acute MS relapses, and is transforming Oculis as an emerging leader in neuro-ophthalmology*
- *Oculis will host a virtual R&D Day in the fourth quarter of 2026 to provide further updates on its clinical pipeline*

ZUG, Switzerland, Aug. 03, 2026 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology, today announced positive U.S. Food and Drug Administration (FDA) pre-IND feedback regarding Privosegtor's clinical development plan in acute multiple sclerosis (MS) relapses.

Privosegtor is a novel peptoid small-molecule candidate with potential neuroprotective properties. In the previously completed Phase 2 ACUITY study, Privosegtor showed a clear neuroprotective effect in optic neuritis, improving visual function, preserving retinal ganglion cell (RGC) layer integrity, and reducing neurofilament levels, a biomarker of axonal injury. Optic neuritis is frequently observed during new onsets of MS or as a typical relapse and serves as a well-established pathophysiological model that is generalizable to potentially all other acute MS relapses. The ACUITY study evaluated a broad population of patients with optic neuritis (ON), including those with and without MS. The ACUITY study provided confidence to investigate Privosegtor in the ongoing PIONEER global registrational program for optic neuritis. Expanding into acute MS relapses is a natural evolution for the Privosegtor program as the Company looks to leverage positive learnings from the ACUITY study and to address additional relapse types.

Oculis requested pre-IND feedback from the FDA to guide its development plans with Privosegtor for a potential new indication in acute MS relapses. The FDA Division of Neurology provided guidance that Oculis could cross-reference data from the open IND and that no additional preclinical studies are required for an IND submission in acute MS relapses. The constructive FDA feedback also supported the proposed clinical development strategy and regulatory pathway, which will include MS patients with both optic neuritis and other relapses, such as ambulatory relapses, in future trials. It also supported a primary endpoint as early as 3 months, with the same 3mg/kg dose administered daily for 5 days as in PIONEER-1. Oculis anticipates an IND submission for the treatment of acute MS relapses in the fourth quarter of 2026.

Riad Sherif, M.D., Chief Executive Officer of Oculis, remarked: "Our recent positive engagement with the FDA supports a regulatory pathway for Privosegtor in acute MS relapses, an area of high unmet need with no currently approved neuroprotective options. Building on positive Phase 2 ACUITY data in optic neuritis, a frequent type of MS relapse, we believe Privosegtor has the potential to mitigate neuroaxonal damage and improve recovery following acute relapse events. This milestone significantly advances our strategy to build a leading neuro-ophthalmology pipeline, and we look forward to sharing further details on PIONEER and this new program at our upcoming R&D event later this year."

Professor Amit Bar-Or, M.D., Chief, Multiple Sclerosis Division, Department of Neurology, Perelman School of Medicine, University of Pennsylvania, added: "I am very encouraged at the prospect of a novel neuroprotective agent such as Privosegtor entering clinical development in acute MS relapses. While immunomodulators are increasingly deployed in practice to reduce the frequency of relapses in MS patients, recovery from an acute event is very rarely complete. The neurodegeneration that occurs during these acute attacks persists after the relapse, leading to an accumulation of disabilities. Privosegtor, as a CNS-penetrant neuroprotective agent, could potentially enhance recovery following relapses and improve long-term outcomes for people with MS."

Oculis management plans to host an R&D Day in the fourth quarter of 2026 to review additional details on the pivotal development program for Privosegtor in acute MS relapses and provide a comprehensive update on the PIONEER program in optic neuropathies.

MS is a chronic immune-mediated disease affecting approximately 2.8 million people worldwide, including around 850,000 in the U.S. alone.[1-3] There are two main types of MS: relapsing-remitting MS (RRMS) and progressive MS. While progressive MS remains a significant unmet medical need, RRMS is the most common type, representing ~85% of patients at initial diagnosis.[2] It is currently managed using immunomodulators or disease-modifying therapies (DMTs) that reduce the rate of relapses and therefore related relapse-associated worsening (RAW). However, relapses still persist for many patients, with an estimated 170,000 MS relapses occurring each year in the U.S.[4]

During an acute relapse, neurologists commonly use a short course of high-dose corticosteroids to reduce inflammation and shorten the episode, as is also standard of care in optic neuritis. However, corticosteroids do not influence the long-term disability, and recovery from relapses is often incomplete, such as in optic neuritis. The tissue damage that occurs during these relapses can contribute to neuroaxonal loss and the accumulation of functional disability over time, underscoring the need for therapies that protect neurons and axons during relapses. There are currently no neuroprotective therapies approved for MS relapses, and there remains an urgent unmet medical need for treatments that can prevent central nervous system damage.

Our recent advancements create a robust clinical development roadmap opportunity for Privosegtor built on two distinct pillars:

- **Immediate Registrational Path**: advancing optic neuritis as our primary registrational indication through PIONEER-1, supported by ACUITY Phase 2 findings across functional, anatomical and biomarker measures and conducted under a Special Protocol Assessment (SPA) with the FDA; and
- **First Expansion Wave**: expanding into acute MS relapses as a natural extension of the optic neuritis program, leveraging the clinical and pathophysiological relevance of optic neuritis as a common MS relapse type and the FDA's constructive feedback on the proposed development pathway.

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 and neurological diseases. Positive results from the ACUITY Phase 2 trial showed Privosegtor's neuroprotective potential, as evidenced by improvements in visual function, corroborated by anatomical preservation of the retina, including GCIPL and RNFL layers, and reduced neurofilament levels in the blood after an acute episode of optic neuritis. Consistent results were observed in animal models of glaucoma, optic neuritis, and multiple sclerosis (MS), where Privosegtor preserved retinal ganglion cells and was associated with improvements in mobility (clinical function disability) in the MS model.

Privosegtor has received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) and Priority Medicines (PRIME) designation from the European Medicines Agency (EMA) as well as Orphan Drug designation from both the FDA and the EMA for ON. Privosegtor is currently being evaluated in Oculis' PIONEER (Privosegtor Investigation in Optic Neuropathies Efficacy Evaluation Research) program, which includes two registrational trials in ON and one registrational trial in non-arteritic anterior ischemic optic neuropathy (NAION). Building on the ACUITY Phase 2 dataset in optic neuritis and constructive FDA pre-IND feedback, Oculis is also planning an IND submission for Privosegtor for the treatment of acute MS relapses.

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

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 focuses on two core product candidates. Privosegtor is a breakthrough neuroprotective candidate in the PIONEER program, which consists of studies intended to support registration plans for treatment of optic neuropathies, including optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION). Privosegtor also has potential to be developed for additional indications in other neuro-ophthalmic and neurological diseases. Licaminlimab is a novel, topical anti-TNFα in a registrational trial, and is being developed with a genotype-based approach for treating patients with dry eye disease (DED). Headquartered in Switzerland with operations in the U.S., Iceland and Switzerland, 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

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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, including the potential of Privosegtor to become the first neuroprotective therapy for ON and other neuro-ophthalmic and neurological indications including acute MS relapses, the initiation, timing, progress and results of current and future clinical trials, including the planned IND submission for Privosegtor in acute MS relapses; the development of a pivotal clinical program for an acute MS relapse indication, including the clinical development strategy, trial design and expected endpoints, as well as the potential for Privosegtor's results in ON to be predictive of outcomes in acute MS relapses; Oculis' research and development programs, regulatory and business strategy; Oculis' future development plans; statements about market opportunity and the ability of Oculis' product candidates to address those markets; and the timing or likelihood of regulatory interactions, filings and approvals, 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 (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:

1. MS National Society
2. Wallin et al., 2019, The prevalence of MS in the United States: A population-based estimate using health claims data - PubMed
3. McGinley et al., 2021, Diagnosis and Treatment of Multiple Sclerosis: A Review - PubMed
4. Multiple sources on relapse rate (ARR) including: Ocrelizumab versus fingolimod after natalizumab cessation in multiple sclerosis: an observational study - PubMed