Oculis Announces FDA IND Clearance Enabling Acceleration of Privosegtor Development Program in Acute Multiple Sclerosis Relapses

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FDA IND clearance opens a new era for Oculis in neurology, initiating clinical development in acute MS relapses by building directly upon the positive Phase 2 ACUITY trial and ongoing PIONEER program in optic neuritis

Oculis will host an R&D Day on December 8, 2026, to provide further updates on the development program for Privosegtor in acute MS relapses and the ongoing PIONEER program in optic neuropathies

ZUG, Switzerland, November 16, 2026 -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) ("Oculis"), a global biopharmaceutical company focused on breakthrough innovations to address critical unmet medical needs in neuro-ophthalmology, neurology, and ophthalmology, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for Privosegtor for the treatment of acute multiple sclerosis (MS) relapses.

The FDA clearance follows pre-IND feedback from the FDA Division of Neurology-2, which confirmed that Oculis can cross-reference data from the open Privosegtor ophthalmology-related IND. The FDA further supported the proposed clinical development strategy, which would include patients with Multiple Sclerosis (MS) who experience Optic Neuritis (ON) as well as other types of relapses, such as ambulatory relapses, and a primary endpoint as early as three months, using the same 3mg/kg daily dose for five days as in PIONEER-1.

Optic neuritis is frequently observed both as the initial clinical presentation of MS and during acute relapses, serving as a pathophysiological model of acute demyelination that is potentially generalizable to other acute MS relapses. In the completed Phase 2 ACUITY study, which evaluated a broad population of patients with ON, including those with and without MS, Privosegtor demonstrated a promising neuroprotective effect. Specifically, it improved visual function, preserved retinal ganglion cell (RGC) layer integrity, and reduced blood levels of both neurofilament light chain (NfL), a biomarker of axonal injury, and glial fibrillary acidic protein (GFAP), a biomarker of astrocytic activation.

Building on these positive findings, expanding into acute MS relapses is a natural evolution for the Privosegtor program. MS affects approximately 2.8 million people worldwide[1], with an estimated 170,000 relapses occurring annually in the U.S. alone[7], representing both a significant clinical opportunity and a critical unmet need. While every relapse carries the risk of permanent nerve damage, current standard-of-care immunomodulators or disease-modifying therapies only shorten attack duration or reduce relapse frequency. Privosegtor has the potential to become the first neuroprotective therapy to actively preserve nerve integrity during acute MS relapses.

"This IND clearance marks a pivotal new era for Oculis in neurology as we advance Privosegtor from optic neuritis into acute MS relapses, addressing a high-unmet-need setting with no currently approved neuroprotective therapies," **said Dr. Riad Sherif, Chief Executive Officer of Oculis.** *"Because optic neuritis is a common manifestation of MS relapse, our positive Phase 2 ACUITY results give us confidence in Privosegtor's potential to limit neuroaxonal damage and support functional recovery following an acute attack. Building on the foundation of our PIONEER registrational program in optic neuritis, we are well-positioned to accelerate the clinical development of Privosegtor in this new indication. We value the FDA's constructive engagement and are excited about the meaningful impact Privosegtor could have on patients experiencing optic neuritis and other MS relapses."*

Amit Bar-Or, MD, Professor of Neurology at the Perelman School of Medicine, University of Pennsylvania, said: *"Even with effective immunomodulating therapies, many people with MS still experience relapses, and recovery from them is often incomplete. A treatment that protects neurons and axons during an acute relapse would fill a gap that no current care addresses. I am encouraged to see Privosegtor moving toward clinical development in acute MS relapses and beyond and look forward to seeing how the data evolve."*

Oculis plans to host an R&D Day on December 8, 2026, to review additional details on the PIONEER program, including the pivotal development program for Privosegtor in acute MS relapses, and provide a comprehensive update on the PIONEER program in optic neuropathies and Acute MS relapse. To register for the event, click here.

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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, neurology, 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, designed to support registrational plans across optic neuropathies, such as optic neuritis (ON) and NAION, as well as acute MS relapses. Privosegtor also offers potential for expansion into additional neuro-ophthalmic and neuro-axonal indications. Licaminlimab is a novel topical anti-TNFα in a registrational trial and is being developed with a genotype-based approach to treat patients with TNFR1 dry eye disease. Headquartered in Switzerland with operations in the U.S. and Europe, 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 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 neuro-axonal 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. Furthermore, the safety profile reported in the ACUITY Phase 2 trial showed no adverse events leading to drug withdrawal or study discontinuation. Consistent results were observed in animal models of glaucoma, optic neuritis and multiple sclerosis, where Privosegtor preserved retinal ganglion cells and was associated with improvements in mobility in the multiple sclerosis model.

Privosegtor has received Breakthrough Therapy designation from the U.S. Food and Drug Administration and Priority Medicines (PRIME) designation from the European Medicines Agency, as well as Orphan Drug designation from both agencies 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.

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

About Multiple Sclerosis (MS)

MS is a chronic autoimmune disease of the central nervous system (CNS) which targets the myelin sheath of axons and the axons themselves, affecting approximately 2.8 million people worldwide[1], including around 850,000 in the U.S. alone.[2-6] The most common form, relapsing-remitting MS (RRMS), accounts for approximately 85% of cases[1] and is characterized by acute inflammatory relapses that can affect the brain, optic nerve, and spinal cord, resulting in episodes of worsening symptoms and disability. RRMS is currently managed using immunomodulators which can reduce the rate of relapses[2]; however, relapses persist for many patients despite treatment, with an estimated 170,000 MS relapses occurring each year in the U.S.[7]

Current treatment of acute MS relapses primarily relies on high-dose corticosteroids to reduce inflammation and shorten the episode, while immunomodulator therapies help reduce relapse frequency. However, neither approach has been proven to directly protect neurons and axons from injury during acute inflammatory events. Tissue injury and the neuroinflammatory toxic microenvironment occurring during 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.[2,8] Despite advances in the long-term management of MS, a significant unmet need remains for therapies that provide neuroprotection during acute relapses, preserve neurological tissues, reduce the risk of functional disability over time and improve the likelihood of optimal recovery.[9,10]

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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 for Privosegtor to become the first neuroprotective therapy for optic neuritis and other neuro-ophthalmic and neuro-axonal diseases and the potential applicability of ACUITY ON results to an acute MS relapse indication; the potential for Licaminlimab to transform the treatment paradigm in dry eye disease with a precision medicine approach; the design, initiation, enrollment, timing, progress and results of current and future clinical trials; Oculis' research and development programs, regulatory and business strategy; Oculis' future development plans; the timing or likelihood of regulatory filings and approvals; and statements about market opportunity, 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 subject to risks, variability and contingencies, many of which are beyond Oculis' control. Results from prior clinical trials may not be replicated in later clinical trials. 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 expected and/or expressed or implied by such forward-looking statements, 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. Oculis undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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