First Patient Treated in PIONEER-1 Registrational Trial of Privosegtor for Optic Neuritis

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The PIONEER program marks a key step toward potential first-in-class neuroprotection for optic neuritis and other neurological diseases, supported by positive Acuity Phase 2 data, FDA Breakthrough Therapy and EMA PRIME designations, and recent positive feedback from the FDA Neurology Division.

ZUG, Switzerland, August 24th, 2026 -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) ("Oculis"), a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology, today announces that the first patient has been treated in the PIONEER-1 registrational trial evaluating Privosegtor for the treatment of optic neuritis (ON).

Riad Sherif, M.D., Chief Executive Officer of Oculis, remarked:
"Treating the first patient in PIONEER-1 at a leading center in the US is a pivotal milestone as we advance our late-stage pipeline while focusing on neuro-ophthalmology. PIONEER-1 is a specialized study, and we are immensely proud of our team and partners' operational execution in activating expert multidisciplinary centers dedicated to managing this complex condition. We are excited to pioneer this novel potential agent for optic neuritis, which could unlock a new paradigm of neuroprotection. If successful, Privosegtor could fill a critical treatment void across optic neuropathies, with broader applicability across neurology, including acute multiple sclerosis relapses."

Privosegtor, a novel peptoid small molecule that can cross the blood-brain and retinal barriers, could become the first neuroprotective therapy for ON, with broad potential applicability in other neuro-ophthalmic and neurological diseases. Following the successful Phase 2 ACUITY trial, Oculis launched the PIONEER (Privosegtor Investigation in Optic Neuropathies Efficacy Evaluation Research) program, which includes two registrational trials in ON. The first registrational trial in the program, PIONEER-1, is evaluating Privosegtor in patients with acute-onset ON across a broad population, including patients with and without multiple sclerosis (MS). The first patient was treated at a leading center in the U.S., Oculis, and our partners have been focused on establishing a robust, multidisciplinary network connecting emergency room physicians, ophthalmologists, and neurologists, as well as patient screening. This integrated approach aims to optimize operational flows from patient identification to treatment, capitalizing on peak enrolment opportunities during the fall, winter, and spring to align with the disease's natural seasonality.

The primary endpoint of PIONEER-1 is the proportion of patients achieving at least a 15-letter gain from baseline, and the secondary endpoint is the mean change in low-contrast visual acuity (LCVA) at Month 3, both clinically meaningful functional endpoints in ON. The primary analysis will be conducted at Month 3, and patients will be followed through Month 12 to assess long-term safety and tolerability. Dosing and patient enrolment criteria will closely mirror those of the Phase 2 ACUITY trial, in which Privosegtor showed substantial improvements in vision at Month 3, which persisted through Month 6, as measured by LCVA, along with consistent anatomical and biological neuroprotective benefits compared with placebo. These positive findings supported the granting of Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) and **Pri**ority **Me**dicines (PRIME) designation by the European Medicines Agency (EMA) for the treatment of ON.

Oculis received written agreement from the FDA, under a Special Protocol Assessment (SPA) agreement, confirming that the design and planned analysis of the PIONEER-1 trial will adequately address the objectives necessary to support an NDA submission in ON, subject to a successful outcome of the trial and review of all the data in the NDA submission.

Building on the ACUITY Phase 2 dataset in ON and based on constructive pre-IND feedback from FDA's Neurology division, Oculis is planning an IND submission for Privosegtor to treat acute MS relapses, anticipated in Q4 2026.

Mark Kupersmith, M.D., Professor, Vice chair of Translational Research, Chair NORDIC at Icahn School of Medicine at Mount Sinai Hospital, New York, added: "For decades, our approach to optic neuritis and other acute MS attacks has stopped at trying to reduce the secondary acute inflammation, while preventing axonal and secondary neuronal loss has not been accomplished. The ACUITY findings fundamentally shift this paradigm by demonstrating that true neuroprotection validated by structural and biological markers of nerve preservation and measurable functional recovery could be clinically achievable. As we advance into the PIONEER-1 trial, the data from this study, if positive, could establish critical insights not only for treating optic neuropathies, but also for how we measure and deliver structural CNS preservation across broader neurodegenerative conditions."

-ENDS-

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. 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 ON 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 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. 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 neuro-axonal 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 for Privosegtor to become the first neuroprotection therapy for optic neuritis and its potential broad applicability across neurology, including in acute MS relapses, the 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 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. Results of earlier stage clinical trials may not be replicated in subsequent clinical trials. 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.

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