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PRESS RELEASE

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Oxurion Announces the Continuation of KALAHARI Phase 2, Part B Study in Diabetic Macular Edema Following Interim Analysis

Trial Continues with Top-line Data Anticipated 2H 2023

Leuven, BELGIUM, Boston, MA, US – December 14, 2022 – 8.00 AM CET – Oxurion NV (Euronext Brussels: OXUR) a biopharmaceutical company developing next generation standard of care ophthalmic therapies, with clinical stage assets in vascular retinal disorders, announced today that an Independent Data Monitoring Committee (IDMC) completed its planned interim analysis of the KALAHARI Phase 2, Part B clinical trial evaluating Oxurion's novel plasma kallikrein (PKal) candidate, THR-149, as a potential treatment for patients who respond suboptimally to anti-VEGF standard of care for treatment of diabetic macular edema (DME).

The IDMC recommended continuation of the study based upon the outcome of the futility analysis. The IDMC assessment included an evaluation of interim efficacy and safety data from three-month data, with a total of 31 patients. Top-line data from the study is anticipated in the second half of 2023.

"We are very pleased to continue the KALAHARI trial following the IDMC's recommendation after their review of our interim data," said Andy De Deene, MD, Chief Development Officer of Oxurion. "This trial is evaluating THR-149 for the treatment of DME against the current standard of care anti-VEGF therapy. THR-149 could provide an important alternative for the up to 50% of patients with DME who respond suboptimally to anti-VEGF."

Oxurion's Chief Executive Officer, Tom Graney, CFA, added that "Continuing this trial based on the results of the interim analysis is a critical milestone for patients with DME, which is the leading cause of blindness in working-age people. We look forward to completing this study, which, if positive, would enable Phase 3 development that could position THR-149 as an important second line therapy in the $5+ billion global DME market."

Diabetic Macular Edema (DME)

Approximately 22 million people worldwide have DME, with prevalence increasing due to the growing global diabetic epidemic. DME is the leading cause of vision loss in working-age people, and the market for treatments is currently estimated at $5+ billion.

People who suffer from DME have leaking vessels in the back of the eye. This leakage leads to a thickening of the retina and causes vision problems. DME may cause blurriness in the center of vision, the appearance of dark spots or patches in the field of vision, and colors to look dull. These symptoms may affect the ability to read, write, drive, and recognize faces – presenting a significant patient and caregiver burden.

Current treatments for DME include inhibitors of vascular endothelial growth factor (VEGF), steroids and laser therapy. However, while anti-VEGF is the mainstay of therapy, up to 50% of patients do not respond optimally. Moreover, the treatment regimen itself presents a high burden: patients must have intravitreal injections on a frequent basis (can be as often as monthly), resulting in a lack of compliance and an increase in loss of vision.

About THR-149
THR-149 is a bicyclic peptide that selectively inhibits human plasma kallikrein (PKal) with an inhibition constant of 0.22 nM. Through the inhibition of the kallikrein-kinin system (KKS), THR-149 prevents the induction of retinal vascular permeability, neurodegeneration, and inflammation.

THR-149 is currently being evaluated in the KALAHARI Phase 2, Part B clinical trial as a potential treatment for patients who respond suboptimally to anti-VEGF standard of care for treatment of DME.

KALAHARI Phase 2, Part B
Part B is the second part of the Phase 2 KALAHARI study, a two-part, randomized, prospective, multi-center study assessing multiple (3) injections of THR-149 in DME patients. Part B is double-masked and actively controlled, with the high dose of THR-149 selected from Part A of the trial being evaluated. Part B of the study is enrolling just over one hundred patients who have previously shown a suboptimal response to anti-VEGF therapy, and where THR-149 is being evaluated against aflibercept, the current standard of care, as the active comparator.

KALAHARI Phase 2, Part A
Part A of the KALAHARI study demonstrated that all dose levels of THR-149 had a favorable safety profile. All adverse events in the study eye were mild to moderate in intensity and no severe ocular adverse events were reported and no inflammation observed. High-level data from Part A of the KALAHARI trial was first presented in October 2021, which demonstrated that the eight patients who received the highest dose of THR-149, achieved a mean BCVA gain of 6.1 letters at Month 3, the primary endpoint. A post-hoc analysis was performed by the masked central reading center in February 2022 based on an OCT (Optical Coherence Tomography) biomarker assessment.

The masked reading center identified two subjects with abnormalities at baseline, which could impact responsiveness to any medical treatment. Excluding these two subjects resulted in an improvement in mean BCVA of 9.3 letters at Month 3, which was sustained until Month 6, the end of the trial. The Month 6 data also demonstrated THR-149's attractive safety profile and its ability to stabilize the Central Subfield Thickness (CST). The learnings from the Part A data were incorporated into Part B through an amended study design excluding patients that would not respond to any treatment. More information can be found here: NCT04527107

About Oxurion
Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard of care ophthalmic therapies, which are designed to improve and better preserve vision in patients with retinal disorders including diabetic macular edema (DME), the leading cause of vision loss in working-age people, as well as other conditions. Oxurion intends to play an important role in the treatment of retinal disorders, including the successful development of THR-149, its novel therapeutic for the treatment of DME. THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the up to 50% of DME patients showing suboptimal response to anti-VEGF therapy. Oxurion is headquartered in Leuven, Belgium, with corporate operations in Boston, MA. More information is available at www.oxurion.com.

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