

Oxurion Announces Interim Analysis for KALAHARI Trial

Interim Analysis for KALAHARI trial planned by Year-End 2022 with Full Top-Line Data Expected in Second half of 2023

Leuven, BELGIUM, Boston, MA, US – November 18, 2022 – 10:00 PM 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, today announced it is planning an interim analysis of at least 25% of the patients for the KALAHARI Phase 2, Part B clinical trial. Results of the interim analysis are expected by year-end 2022 and full top-line data from the trial is now expected in the second half of 2023.

The KALAHARI trial is 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 Phase 2 KALAHARI study is a two-part, randomized, prospective, multi-center study assessing multiple injections of THR-149 in DME patients who have previously shown a suboptimal response to anti-VEGF therapy. Part B follows Part A of the study, in which three dose levels of THR-149 (0.005mg, 0.022mg and 0.13mg), were each administered in three monthly IVT injections, were evaluated in order to select the best dose for Part B of the study.

High-level Month 3 data from Part A of the KALAHARI trial was first presented in October 2021 and demonstrated that in the eight patients who received the highest dose of THR-149, a mean BCVA gain of 6.1 letters at Month 3, the primary endpoint, was observed. A post-hoc analysis of an OCT (Optical Coherence Tomography) biomarker assessment, was performed by the masked central reading center in February 2022. 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 that was sustained until Month 6, the end of the trial. The six-month 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. 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. 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](#).

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking

statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company's Annual Report. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of Oxurion in any jurisdiction. No securities of Oxurion may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. state securities laws.

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