

Oxurion Reaches Enrollment Target in KALAHARI Phase 2, Part B Trial of Novel PKal Inhibitor THR-149 in Diabetic Macular Edema

Top-line Data Anticipated in Q4 2023

Leuven, BELGIUM, Boston, MA, US – May 25, 2023 – 9:00 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, announced today that it has reached its enrollment target of 108 patients randomized in its KALAHARI Phase 2, Part B clinical trial for diabetic macular edema (DME) (KALAHARI trial).

As of today, Oxurion’s investigators have successfully enrolled the 108 patients planned for this trial. Given the high level of interest from both investigators and patients, additional patients are still likely to be included in the trial, which would mean the trial will be over-enrolled.

As it has now reached its enrollment target, Oxurion confirms its previous guidance that it anticipates reporting top-line data from the KALAHARI trial in the fourth quarter of 2023.

“We are thrilled to reach our enrollment target in the KALAHARI trial, and the fact that we are likely to over-enroll is further testament to both the need for this therapy as well as the continued support of our investigators worldwide,” said Andy De Deene, MD, MBA, Chief Development Officer of Oxurion. “The outcome of this trial, which is evaluating THR-149 for the treatment of DME against the current standard of care, aflibercept, could, if positive, provide an important alternative for the up to 50% of patients with DME who respond suboptimally to current anti-VEGF therapies.”

Added Tom Graney, CFA, CEO of Oxurion, said, “Attaining this milestone is an important catalyst for Oxurion as we move towards completion of the KALAHARI trial. With the enrollment target reached, the study is well-positioned to report top-line results by the end of the year. If positive, these results could provide a meaningfully better alternative for the millions of patients worldwide suffering from DME for whom current treatments are not effective. I would like to thank the investigators, their teams, our amazing team, and most of all the patients, for progressing this important trial on behalf of the broader retinal community.”

The KALAHARI trial is evaluating Oxurion’s novel plasma kallikrein (PKal) inhibitor THR-149 as a potential treatment for DME patients who respond suboptimally to anti-VEGF therapy, the current standard of care. This milestone follows the recommendation from an Independent Data Monitoring Committee (IDMC) in December 2022 that the KALAHARI trial should continue based on the outcome of a pre-specified futility analysis that included an evaluation of interim efficacy and safety data from 31 patients at the three-month time point.

Diabetic Macular Edema (DME)

Approximately 22 million people worldwide have DME currently, 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, leading to a thickening of the retina that causes vision problems such as 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.

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 the standard of care for treatment of DME.

KALAHARI Phase 2, Part B

The Phase 2 KALAHARI trial is a two-part, randomized, prospective, multi-center trial 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 having been selected from Part A of the trial. Part B of the trial is enrolling approximately 108 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 trial 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 was 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 analysis 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, and four months after the last THR-149 injection. 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 trial design excluding patients that would not respond to any treatment. More information can be found here: [NCT04527107](https://clinicaltrials.gov/ct2/show/study/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.

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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