

## **Oxurion Announces New Data on THR-149 Phase 2 Clinical Trial (“KALAHARI”) in DME at the Angiogenesis, Exudation, and Degeneration 2022 Conference**

- **Post-hoc analysis reveals >9 letter gain in mean BCVA that was maintained for the remaining four months of the trial after the last THR-149 injection with no rescue treatment required**
- **These gains were seen in patients that are part of the 40-50% of DME patients that suboptimally respond to standard of care anti-VEGF therapy**

Leuven, BELGIUM, Boston, MA, US – 14 February 2022 – 8.00 AM CET – [Oxurion NV](#) (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard of care ophthalmic therapies, with a clinical stage portfolio in vascular retinal disorders, presented new data from Part A of its two-part Phase 2 Clinical Trial (“KALAHARI”) assessing THR-149 for treatment of diabetic macular edema (DME) at the Angiogenesis, Exudations, and Degeneration 2022 Meeting on February 11-12th.

THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy. High-level Month 3 data from Part A of the KALAHARI trial was first presented in October 2021 and demonstrated that in the 8 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.

The new data reviewed today is a post-hoc analysis of an OCT (Optical Coherence Tomography) biomarker assessment, which was performed by the masked central reading center. The masked reading center identified two subjects with abnormalities at baseline, which could impact responsiveness to 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 data presented today continues to highlight THR-149’s compelling safety and efficacy profile in patients with diabetic macular edema,” commented Arshad M. Khanani, M.D., M.A., Director of Clinical Research at Sierra Eye Associates, Reno, Nevada, US. “For patients who are suboptimal responders to standard of care anti-VEGF therapy, the post-hoc analysis of the high-dose cohort in the KALAHARI trial showed encouraging gains in BCVA with over 80% of patients gaining at least 5 letters and 50% of patients gaining at least 10 letters four months after the last THR-149 injection. In addition, CST was stable up to Month 6. These results demonstrate the potential of THR-149 to make a meaningful difference to this patient population, which if left untreated would be expected to experience a further deterioration in their vision.”*

Based on Month 3 Part A data, the high dose of THR-149 was selected for Part B of the KALAHARI study to compare vs. aflibercept for the treatment of DME. The learnings from the Part A data presented today have already been incorporated into Part B through an amended study design, which has been

approved by the US IRB. The approved protocol amendment optimizes the inclusion and exclusion criteria for Part B and eliminates subjects with potential baseline abnormalities, to further increase the potential for response to treatment. Part B of the trial is currently enrolling with topline data expected mid-2023.

**Tom Graney, CFA, Chief Executive Officer of Oxurion, said,** *“The data Dr. Khanani presented improves our understanding of which patients are most likely to respond to treatment and underscores the potential of THR-149 to address the significant unmet need in patients that experience a suboptimal response to anti-VEGFs and currently lack adequate treatment options. We believe these changes will maximize our ability to achieve a successful trial outcome to the benefit of patients while preserving the positive attributes of the initial trial design and maintaining our timelines.”*

Part B of the KALAHARI trial is ongoing, assessing three monthly injections of THR-149, compared to three monthly injections of aflibercept, up to Month 3. As from Month 3, the safety and efficacy of a switched fourth injection (THR-149 to aflibercept or aflibercept to THR-149) will be evaluated in about half of the subjects whereas in the other half of the subjects the durability of three monthly injections (THR-149 or aflibercept) will be assessed through a single sham injection. The trial is planned to randomize approximately 108 subjects in Part B and the primary endpoint remains the mean change in BCVA letter score from baseline, at Month 3.

All dose levels of THR-149 demonstrated a favorable safety profile during Part A of the KALAHARI trial, which was maintained through the end of the trial. All adverse events in the study eye were mild to moderate in intensity and no severe ocular adverse events were reported and no intra-ocular inflammation observed.

### **About Oxurion**

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard of care ophthalmic therapies, which are designed to better preserve vision in patients with retinal vascular disorders including diabetic macular edema (DME), the leading cause of vision loss in diabetic patients worldwide as well as other conditions, including wet age-related macular degeneration (wAMD) and retinal vein occlusion (RVO).

Oxurion is aiming to build a leading global franchise in the treatment of retinal vascular disorders based on the successful development of its two novel therapeutics. THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy. THR-687 is a highly selective pan-RGD integrin antagonist that is being developed as a potential first line therapy for DME patients as well as wAMD and ME-RVO. Oxurion is headquartered in Leuven, Belgium, with corporate operations in Boston, MA. More information is available at [www.oxurion.com](http://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 an 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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