

OXURION NV - First Patient Dosed in Part B of Phase 2 KALAHARI Study Evaluating Multiple Administrations of THR-149 versus aflibercept for Treatment of Diabetic Macular Edema (DME)

THR-149 is a potent plasma kallikrein inhibitor for the treatment of DME in the roughly 50% of the patient population suboptimally responding to anti-VEGF therapy

Leuven, BE, Boston, MA, US – 15 November 2021 – 07.00 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, announces the first patient has been dosed in Part B of its two-part, Phase 2 study (“KALAHARI”) evaluating multiple injections of THR-149 for the treatment of DME.

THR-149 is being developed to potentially become the treatment of choice for the 40-50% of DME patients who respond suboptimally to anti-VEGF therapy. THR-149 acts through inhibition of the plasma kallikrein-kinin (PKaI-Kinin) system, a validated VEGF-independent target for DME treatment.

The primary objective of part B of the study is to assess the difference in treatment effect between the selected dose from part A of THR-149 (0.13mg) and aflibercept from Baseline to Month 3, in terms of increase in best-corrected visual acuity (BCVA), the primary endpoint.

Tom Graney, CFA, Chief Executive Officer of Oxurion, comments, “After the success of Part A, we are very happy to begin Part B of the Phase 2 KALAHARI study evaluating THR-149 for the treatment of DME against the current standard of care. Positive results from this Phase 2 trial would confirm THR-149’s potential to provide a much-needed treatment option for DME patients who fail to respond or respond suboptimally to existing anti-VEGF treatment. The success of this study would pave the way to a pivotal trial, that if successful, could position THR-149 to capture an important share of and expand the \$4.5 billion DME market, which at the moment is almost entirely served by anti-VEGF therapies.

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. This part of the study will enroll just over one hundred patients, who have previously shown suboptimal response to anti-VEGF. In Part B of the study, which is double-masked and actively controlled, the high dose of THR-149 selected from Part A of the trial will be evaluated against aflibercept as the active comparator.

Final topline results from Part B of the study are expected mid 2023.

Positive Results of Part A of the Study

Clinical results from Part A of the KALAHARI study, which recruited patients who had responded suboptimally to anti-VEGF therapy, demonstrated that all dose levels of THR-149 had a positive safety profile. The side-effects observed in patients were mild to moderate in intensity and there were no cases of severe ocular inflammation.

In terms of efficacy, a rapid onset of action was observed with the highest dose of THR-149 (0.13mg) delivering the greatest improvement in mean best corrected visual acuity (BCVA) of 6.1 letters at Month 3. Within this group, 63% of patients showed at least a 5-letter gain, 38% achieved at least a 10-letter gain, and 13% achieved at least a 15-letter gain at Month 3.

Oxurion intends to present a more complete data set from Part A of the KALAHARI study at an upcoming leading ophthalmology conference.

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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 (AMD) and retinal vein occlusion (RVO).

Oxurion is aiming to build the leading global franchise in the treatment of retinal vascular disorders based on the successful development of its two novel therapeutics:

- THR-687 is a highly selective pan-RGD integrin antagonist that is initially being developed as a potential first line therapy for DME patients. Positive topline results in a Phase 1 clinical study assessing THR-687 as a treatment for DME were announced in 2020. Oxurion is currently conducting a Phase 2 clinical trial ("INTEGRAL") evaluating THR-687 in patients with DME. THR-687 also has the potential to deliver improved treatment outcomes for patients with wet AMD and RVO.
- 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-149 has shown positive topline Phase 1 results for the treatment of DME. The Company is currently conducting a Phase 2 clinical trial ("KALAHARI") evaluating multiple injections of THR-149 in DME patients previously showing a

suboptimal response to anti-VEGF therapy. Following positive data from Part A of this Phase 2 study (dose selection), the Company is enrolling subjects in Part B of the study.

Oxurion is headquartered in Leuven, Belgium, and is listed on the Euronext Brussels exchange under the symbol OXUR. 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 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.