

Oxurion NV Announces First Patient Dosed in its Phase 2 Study Evaluating THR-687 for the treatment of Diabetic Macular Edema (DME)

- *THR-687 is a potent pan-RGD integrin antagonist holding potential as a next generation first line therapy for DME, currently a \$4.5 billion market opportunity*
- *THR-687 also holds promise for treatment of wet AMD (Age-related Macular Degeneration) and RVO (Retinal Vein Occlusion) thereby expanding the combined addressable annual market potential to \$12 billion*

Leuven, BE, Boston, MA, US – October 13, 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 that the first patient has been dosed in its Phase 2 clinical study evaluating THR-687 in patients with Diabetic Macular Edema (DME) (study name “INTEGRAL”).

Tom Graney, CFA, Chief Executive Officer of Oxurion, comments: *“We are delighted to have dosed the first patient in Part A of this important Phase 2 clinical trial designed to assess multiple doses of THR-687 in treatment naïve patients suffering from DME. We believe that THR-687, based on its differentiated mode of action and the data generated to date, has the potential to become a first line treatment option for DME patients who require much better clinical outcomes. Beyond DME, THR-687 also holds promise to improve the standard of care of patients with wet AMD and RVO, altogether unlocking a \$12 billion annual market opportunity. In addition to this important milestone with THR-687, we have recently announced positive Phase 2 data from Part A of the KALAHARI study evaluating THR-149 in patients who have responded suboptimally to anti-VEGF therapy, which could allow us to grow the \$4.5 billion DME market. With THR-687 and THR-149, Oxurion has the potential to help millions of patients with eye disease achieve improved vision and to create significant value for our shareholders.”*

The INTEGRAL study is a Phase 2, randomized, multicenter trial and is the first study in which multiple intravitreal injections of THR-687 will be administered in humans.

The two-part study will assess two dose levels of multiple THR-687 injections (Part A) and, if successful, go on to evaluate the efficacy and safety of THR-687 versus aflibercept (the current standard of care) for the treatment of DME (Part B).

Part A is being conducted in treatment naïve subjects to select the optimal THR-687 dose level to be assessed in Part B.

Part B will be conducted in both treatment naïve and treatment experienced subjects to evaluate the efficacy and safety of THR-687 compared to aflibercept.

The primary efficacy endpoint of the study in Part B is the change in Best Corrected Visual Acuity (BCVA) from baseline at Month 3.

The dose selection decision, following Part A, is anticipated in the first half of 2022 with top line data from Part B expected in the second half of 2023.

Arshad M. Khanani, M.D., M.A., Director of Clinical Research at Sierra Eye Associates, Reno, Nevada, US, said, *“I am very pleased to be a part of this important Phase 2 study assessing multiple doses of THR-687 in treatment naïve patients with DME. My enthusiasm for THR-687 is based on the unique mechanism of action and my earlier involvement in the Phase 1 study, which showed THR-687 was well-tolerated and showed an encouraging efficacy signal with a single dose. The novel mechanism of THR-687 is exciting and it has the potential to become the first line treatment of choice for the 28 million patients worldwide who suffer with DME.”*

Oxurion has already generated positive data from a Phase 1, open-label, multicenter (US), single dose escalation study evaluating the safety of a single intravitreal injection of 3 dose levels (0.4 mg, 1.0 mg, 2.5 mg) of THR-687 for the treatment of DME.

A single injection of THR-687 was safe and well-tolerated, showing a very encouraging efficacy signal. Across all doses, a rapid onset of action in mean BCVA was observed from Day 1 with an increase of 3.1 letters, which further improved to 9.2 letters at Month 1. The mean BCVA improvement was maintained with 8.3 letters gain at Month 3 following a single injection of THR-687.

A dose response was seen with the greatest positive effect on BCVA and Central Subfield Thickness (CST) with the highest dose of THR-687. For this highest dose, a mean BCVA improvement of 11 letters was noted at Day 14, with a peak improvement of 12.5 letters at Month 3. Similarly, a peak mean CST decrease of 106 µm was observed at Day 14 with the highest dose of THR-687.

Beyond DME, THR-687 has the potential to be developed for additional vascular retinal disorders including for wet Age-related Macular Degeneration (wet AMD) and Retinal Vein Occlusion (RVO).

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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 a 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 has initiated 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.