

OXURION Confirms Institutional Review Board Approval and Submission of the Investigational New Drug Application to the FDA to Start Phase 2 Study Evaluating THR-687 for Diabetic Macular Edema (DME)

THR-687 is a potent pan-RGD integrin antagonist holding potential as next generation first line therapy for DME

Leuven, BE, Boston, MA, US – June 10, 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 it has received Institutional Review Board (IRB) approval to initiate a Phase 2 clinical study of THR-687 in patients with Diabetic Macular Edema (study name “INTEGRAL”). Together with its earlier submission to the U.S. Food and Drug Administration (FDA) of the final protocol to the Investigational New Drug (IND) Application, this is an important step forward for the Phase 2 INTEGRAL study.

Tom Graney, CFA, Chief Executive Officer of Oxurion, comments: *“Together with our earlier submission to the FDA of the final protocol to the IND, IRB approval for the THR-687 Phase 2 trial in DME is an important milestone for OXURION. This follows the completion of enrolment of Part A in our Phase 2 program evaluating THR-149 in DME as we announced earlier this week. The team is now ready to also start this second Phase 2 program, and we are looking forward to working alongside a large team of enthusiastic investigators across the US and Europe, together creating new paths towards improved therapies for treatment of DME, a very important area of unmet medical need in diabetic eye disease.”*

Today’s announcement follows the positive data reported from a Phase 1, open-label, multi-center (US), single dose escalation study (n=12) evaluating the safety of a single intravitreal injection of 3 increasing doses (0.4 mg, 1.0 mg, 2.5 mg) of THR-687 for the treatment of DME.

A single injection of THR-687 was reported 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. This activity was maintained with a mean BCVA improvement of 8.3 letters at Month 3 following a single injection of THR-687.

A clear 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 also has development possibilities in additional vascular retinal disorders including for wet Age-related Macular Degeneration (wet AMD) and retinal vein occlusion (RVO), thereby potentially allowing the Company to tap into a broader therapeutic market with a current combined estimated annual value of \$12+ billion.

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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-149 is a plasma kallikrein inhibitor being developed as a potential new standard of care for the 40% of DME patients who respond suboptimally 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 evaluating multiple injections of THR-149 in DME patients who previously responded suboptimally to anti-VEGF therapy.
- THR-687 is a 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. THR-687 is expected to enter a Phase 2 clinical trial in mid-2021. THR-687 also holds the potential to deliver improved treatment outcomes for patients with wet AMD and RVO.

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.