OXURION Completes Patient Enrollment for Part A of Phase 2 Study Evaluating THR-149 for Treatment of Diabetic Macular Edema (DME)

THR-149 is a potent plasma kallikrein inhibitor for the treatment of DME in the roughly 40% of the patient population responding suboptimally to anti-VEGF therapy

Leuven, BE, Boston, MA, US – June 8, 2021 – 07.00 AM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard of care ophthalmic therapies, today announced the completion of patient enrollment into Part A of its two part Phase 2 study ("KALAHARI") evaluating multiple injections of THR-149 for the treatment of DME. Dose selection data from Part A of the study is expected in the second half of 2021.

THR-149, Oxurion's most advanced drug candidate, is being developed to potentially become the treatment of choice for the up to 40% 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.

A single dose Phase 1 study showed that THR-149 was well-tolerated, safe and delivered promising efficacy results, particularly improvements in patients' Best Corrected Visual Acuity (BCVA) the primary endpoint for registration in DME. A rapid onset of action was observed from Day 1, across all doses, with an increasing average improvement in BCVA of up to 7.5 letters at Day 14. Importantly, this visual gain was maintained with an average improvement in BCVA of 6.4 letters at Day 90.
The Phase 2 KALAHARI study is a two part, randomized, prospective, multi-center study assessing multiple (3) injections of THR-149 in DME patients who suboptimally respond to anti-VEGF therapy. In Part A of the study, three dose levels of THR-149, each administered in 3 monthly intravitreal injections, are being tested in at least 18 patients to select the optimal dose for Part B.

Tom Graney, CFA, Chief Executive Officer of Oxurion, comments, "*We are very pleased to announce the completion of patient enrollment into Part A of our Phase 2 study evaluating THR-149 for the treatment of DME, particularly given the challenges posed by the continuing Covid-19 situation. This milestone positions us to report the important initial Part A data in the second half of the year. These data, if positive, will provide proof of concept and be a significant derisking event for the company. This patient population currently does not have adequate treatment options and represents a critical area of unmet medical need in the treatment of diabetic macular edema.*"

Part B (n≈104) is the double-masked, active-controlled part of the study with the dose selected from Part A studied against aflibercept as the active comparator. Final topline results from Part B of the study are expected in the first half of 2023.

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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, 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 has 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.