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PRESS RELEASE

Oxurion NV Reports First Patient Dosed in Phase 2 study evaluating THR-149 for treatment of Diabetic Macular Edema (DME)

THR-149 is a potent plasma kallikrein inhibitor in development for DME for up to 40% of patients who respond sub-optimally to anti-VEGF therapy.

- Part A of the study will assess the optimal dose from 3 different dose levels of 3 THR-149 injections – read out anticipated around mid-2021
- Part B of the study will then evaluate the efficacy and safety of the selected optimal dose of THR-149 versus aflibercept for the treatment of DME – read out anticipated in first half of 2023

Leuven, Belgium, 1 September – 07.00 AM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company engaged in the development of next-generation therapies to treat diabetic eye disease, with a focus on Diabetic Macular Edema, today reports that the first patient has been dosed in its two-part Phase 2 study *("KALAHARI")* evaluating THR-149 for the treatment of DME. THR-149 acts through inhibition of the Plasma Kallikrein-Kinin (PKaI-Kinin) system, a validated VEGF independent target for DME.

In a Phase 1 study reported in mid-2019, THR-149 was shown to be well-tolerated and safe. No dose-limiting toxicities nor drug-related serious adverse events were reported at any of the dosages evaluated in the study.

The Phase 1 study also delivered promising results in relation to efficacy, particularly improvements in patients' Best Corrected Visual Acuity (BCVA). 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 following a single injection of THR-149.

The Phase 2, with study name 'KALAHARI', is a randomised, prospective, multi-centre study assessing multiple (3) injections of THR-149 in 2 parts. Part A *(n=18)* is a single-masked, dose-finding part of the study assessing 3 dose levels of THR-149 to select the optimal dose for Part B. Part B *(n≈104)* is the double-masked, active-controlled part of the study with 1 dose level of THR-149 and aflibercept as comparator.

The study will recruit approximately 122 patients with central-involved DME who sub-optimally respond to anti-VEGF across the two parts of the study, with Part A data expected by mid 2021, and top line results from Part B expected in the first half of 2023.

Charles C. Wykoff, M.D., Ph.D., board-certified Medical and Surgical Retina Specialist and Director of Research at Retina Consultants of Houston, and principal investigator of the study said: "*Starting this clinical trial is an important step towards potentially bringing THR-149, a novel and promising plasma kallikrein inhibitor, to patients with DME. DME is a leading cause of adult visual loss globally and new approaches are needed for the up to 40% of patients who do not respond optimally to anti-VEGF monotherapy. These patients may benefit from therapeutics with new mechanisms of action such as inhibition of plasma kallikrein. THR-149 has shown encouraging early clinical data and I look forward to the results from this robust Phase 2 clinical study*."

Grace Chang, M.D., Ph.D., Chief Medical Officer of Oxurion, said: "*We are delighted to announce the recruitment of the first patient into this Phase 2 study with THR-149 in DME, which we have been able to start safely, taking into account the necessary Covid-19 precautions. The data from the Phase 1 study with THR-149 showed that it delivered promising efficacy results in relation to BCVA after a single injection as well as having a rapid onset of action. We believe that this Phase 2 study will further elucidate the clinical benefits that THR-149 could deliver for patients with DME.*"

Patrik De Haes, M.D., CEO of Oxurion, said: "*We believe that THR-149 has the potential to become an important therapy for the large number of patients that have failed to optimally respond to anti-vascular endothelial growth factor (VEGF) therapies.*

The start of this Phase 2 trial is a major step in our plans to build a DME franchise based on the successful development of THR-149 and THR-687 for specific, complementary target patient groups. By successfully developing these two novel therapeutic candidates, we have the potential to transform the treatment of DME patients globally."

Oxurion's emerging DME franchise will be based on the successful development of both THR-149 and THR-687 two novel therapeutics with different modes of action designed for specific complementary target patient groups:

- Oxurion's most advanced new drug candidate, THR-149 is being developed to potentially become the treatment of choice for DME patients with persistent edema who are currently sub-optimally responding to anti-VEGF therapy
- Oxurion's second drug candidate targeting DME, THR-687 is expected to enter Phase 2 development in 2021. This potentially best-in-class pan-RGD integrin antagonist has the potential to become the standard of care for treatment-naïve patients by replacing anti-VEGF's as the mainstay of DME therapy today.

Oxurion is confident that with both THR-687 and THR-149 it will be able to provide new tailored therapeutic solutions that deliver improved clinical outcomes to almost all DME patients.

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard ophthalmic therapies, which are designed to better preserve vision in patients with diabetic macular edema (DME), the leading cause of vision loss in diabetic patients worldwide.

Oxurion is building a leading global franchise in the treatment of DME, 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 DME patients who respond sub-optimally 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 THR-149 with DME-patients who previously responded sub-optimally to anti-VEGF therapy. THR-149 was developed in conjunction with Bicycle Therapeutics PLC (NASDAQ: BCYC)

- THR-687, is a pan-RGD integrin inhibitor, that is initially being developed as a potential new standard of care for all DME patients

  Positive topline results in a Phase 1 clinical study assessing it as a treatment for DME were announced in January 2020. THR-687 is expected to enter a Phase 2 clinical trial by mid 2021. THR-687 is an optimized compound derived from a broader library of integrin inhibitors in-licensed from Galapagos NV (Euronext & NASDAQ: GLPG).

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.