Oxurion NV announces full enrollment of its Phase 2 trial evaluating efficacy and safety of the combination of anti-PlGF (THR-317) and anti-VEGF (ranibizumab) for the treatment of DME, ahead of schedule

Leuven, Belgium, April 4th 2019 – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing innovative treatments to preserve vision in patients with diabetic eye disease, announces today that all patients have been enrolled in its Phase 2 trial evaluating its THR-317, a humanized antibody against placental growth factor (PlGF), in combination with anti-VEGF (ranibizumab), an anti-vascular endothelial growth factor (VEGF) antibody, for the treatment of Diabetic Macular Edema (DME). A total of 70 patients were enrolled in the study, ahead of schedule. Topline data from the study are expected by Q3 2019.

The purpose of the proof of concept study is to evaluate the safety and efficacy of 3 monthly intravitreal injections of THR-317 and ranibizumab in subjects with center-involved DME (CI-DME). The combination of ranibizumab and sham is used as control. Patients will be followed up until 3 months after the last injection (NCT03499223).

Positive data from an earlier Phase 1/ 2 study with THR-317 (mono), demonstrated the safety and tolerability of THR-317 for intra-ocular use. Moreover, reported Day 90 data indicated that 30% of anti-VEGF treatment naïve patients (n=40) had a 3 line or more (≥15 letters) gain in Best Corrected Visual Acuity (BCVA) after 3 monthly injections with THR-317 (8mg). Day 150 showed that 30% of the 8mg anti-VEGF treatment naïve group still showed ≥ 10 letters vision gain.

DME is the result of an accumulation of fluid in the macula – the part of the retina that controls detailed vision - due to leaking blood vessels. DME represents an area of unmet medical need as the current standard of care treatment with anti-VEGF has been shown to deliver suboptimal results in a significant number of patients. It is believed that simultaneously inhibiting VEGF (ranibizumab) and PlGF (THR-317) could deliver incremental benefit over either treatment alone.

Patrik De Haes, M.D., CEO of Oxurion nv, **comments**: "*We are delighted to announce the earlier than anticipated full enrollment of our Phase 2 study evaluating THR-317 in combination with ranibizumab for the treatment for DME. This proof of concept clinical study will for the first time provide important insights into the additional effect anti-PlGF (THR-317) could provide on top of anti-VEGF therapy, the current standard of care for treating DME patients.*"

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For further information please contact:

Oxurion NV Wouter Piepers, Global Head of Investor Relations & Corporate Communications +32 16 75 13 10 / +32 478 33 56 32 wouter.piepers@oxurion.com	
EU - Citigate Dewe Rogerson David Dible/ Sylvie Berrebi Tel: +44 20 7638 9571 oxurion@citigatedewerogerson.com	US - LifeSci Public Relations Alison Chen +1 646-876-4932 achen@lifescipublicrelations.com

About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company currently developing a competitive pipeline of disease-modifying drug candidates for diabetic eye disease, a leading cause of blindness of people of working age worldwide.
Oxurion's most advanced drug candidate is THR-317, a PlGF inhibitor for the treatment of diabetic macular edema (DME), which is currently in a Phase 2 study in combination with Lucentis®. THR-317 is also being evaluated in a Phase 2 study for the treatment of Idiopathic Macular Telangiectasia Type 1 (MacTel 1), a rare retinal disease that affects the macula and can lead to vision loss.
Oxurion has two further pipeline candidates, THR-149, a plasma kallikrein inhibitor being developed for the treatment of DME; and THR-687, a pan-RGD integrin antagonist in development for the treatment of diabetic retinopathy and DME. Both THR-149 and THR-687 are in Phase 1 clinical studies.
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.