Oxurion NV announces full enrollment in its Phase 1 trial evaluating the safety of its plasma kallikrein inhibitor THR-149 for treatment of DME, ahead of schedule

Leuven, Belgium, 24 April 2019 – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing innovative treatments to preserve vision in patients with diabetic eye disease, announces today that it has completed enrollment of its Phase 1 study of THR-149, a novel plasma kallikrein (PKal) inhibitor for the treatment of Diabetic Macular Edema (DME). A total of 15 patient have been recruited. The study enrolled faster than anticipated and initial data will be released by early Q3 2019.

The Phase 1 trial is designed to evaluate the safety of a single intravitreal (IVT) injection of THR-149 a novel PKal inhibitor, of 3 ascending dose levels in subjects with visual impairment due to center-involved DME (CI-DME) (NCT03511898).

Activation of the PKal enzyme has been shown to induce retinal vascular permeability, microaneurysm and inflammation. Based on literature data, patients with DME have elevated levels of plasma kallikrein.

Encouraging preclinical studies involving THR-149 were published in The Journal of Medicinal Chemistry in March 2018. These data demonstrate the potency and efficacy of bicyclic peptide inhibitors of PKal, such as THR-149, via a VEGF-independent pathway.

Patrik De Haes, M.D., CEO of Oxurion nv, commented: “We are delighted to have completed patient recruitment in this important clinical trial earlier than anticipated. This study has been designed to assess THR-149’s safety profile and to provide the information needed to plan the future clinical development plan of this novel plasma kallikrein inhibitor for the treatment of DME.”

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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 in 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.