

Oxurion NV Reports Additional Positive Topline Data from Phase 1 with THR-149, a novel, potent plasma kallikrein inhibitor for DME

- **Immediate onset of action** - starting from Day 1 with increasing average improvement in Best Corrected Visual Acuity (BCVA) of up to 7.5 letters at Day 14 following a single injection of THR-149.
- **Prolonged durability of effect** - average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149.
- **Macular Volume correlated with improvement in BCVA**
- **THR-149 is well-tolerated and safe.** No dose-limiting toxicities or drug-related serious adverse events reported.

Leuven, Belgium , 9 September 2019 – 5.40 PM CET – [Oxurion NV](#) (Euronext Brussels: OXUR), a biopharmaceutical company developing innovative treatments to preserve vision in patients with diabetic eye disease, today reported additional positive topline data from a Phase 1 study with THR-149, a novel, potent, plasma kallikrein (PKal) inhibitor for the treatment of Diabetic Macular Edema (DME).

This Phase 1 open-label, multicenter (US), non-randomized trial evaluated the safety of a single intravitreal (IVT) injection of THR-149, a novel PKal inhibitor, at 3 ascending dose levels in 12 subjects with visual impairment due to center-involved DME (CI-DME) (*NCT03511898*). THR-149 has been developed in partnership with Bicycle Therapeutics (Nasdaq: BCYC). Oxurion holds the exclusive license to the PKal inhibitor portfolio originating from this partnership.

Topline data from the trial show that THR-149 is 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 study looked at efficacy including changes to the patient's Best Corrected Visual Acuity (BCVA), Mean CST (Central Subfield Thickness) and MV (Macular Volume)

A rapid onset of action was observed from Day 1, with an increasing average improvement in BCVA of up to 7.5 letters at Day 14. This activity was maintained with an average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149. In addition, mean BCVA gain was fast and maintained until end of study.

CST change was within the variability of measurement. Macular Volume correlates with BCVA improvement.

Pravin Dugel, M.D., Managing Partner of Retinal Consultants of Arizona and Clinical Professor of Roski Eye Institute, Keck USC School of Medicine, commented on the study results, *“The immediate onset of action and the duration of the BCVA improvement following 1 injection of THR 149 are impressive. Mean CST findings are within variability of measurement. Macular Volume correlates with reported BCVA improvement, potentially offering a new anatomical predictor for BCVA improvement. Overall, the data from this study clearly warrant further clinical research with multiple injections of THR-149.”*

Patrik De Haes, M.D., CEO of Oxurion, said: *“These positive findings provide us with the information and confidence needed to plan the next stage of THR-149’s clinical development. They also demonstrate that THR-149 has the clinical profile to potentially become the best-in-class PKA inhibitor and VEGF independent therapy for the treatment of DME. We are currently preparing to initiate a Phase 2 study with multiple injections of THR-149 and anticipate the enrollment of the first patient in early 2020.”*

Full data from this Phase 1 study will be presented and discussed Dr Pravin Dugel during Retina Society Meeting on Sunday 15 September 2019 in London, UK.

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company currently developing a competitive pipeline of three disease-modifying clinical drug candidates for diabetic eye disease, a leading cause of blindness in people of working age worldwide. The pipeline comprises:

- THR-149, a plasma kallikrein inhibitor, that has shown positive topline Phase 1 results for the treatment of DME. The Company is currently preparing to conduct a Phase 2 clinical program, which is expected to start in H1 2020
- THR-317, a PIGF inhibitor is being evaluated for treatment of diabetic macular edema (DME), as well as 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
- THR-687, a pan-RGD integrin antagonist, which is in a Phase 1 clinical study assessing it as a treatment for diabetic retinopathy and DME. Topline results from this study are expected in late 2019

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.