

Oxurion NV Reports Topline Month 3 Results of Phase 2a Study Evaluating THR-317 (anti-PLGF), in Combination with Ranibizumab, for DME

Regulated Information – Inside Information

- Combination therapy did not show increase in BCVA in the overall population at Month 3.
- Certain improvement in mean BCVA at Month 3 observed with the combination therapy in 2 pre-specified subgroups:
 - poor (or non) responders to prior anti-VEGF
 - patients with poor vision - baseline BCVA \leq 65 letters
- Topline data confirm THR-317 in combination with ranibizumab is safe and well-tolerated

Leuven, Belgium , 20 August 2019 – 07.30 AM CET – [Oxurion NV](#) (Euronext Brussels: OXUR), a biopharmaceutical company developing innovative treatments to preserve vision in patients with diabetic eye disease, today reports topline data from a Phase 2a study evaluating 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).

The Phase 2a randomized, single-masked, active-controlled, multicenter study evaluated the safety and efficacy of 3 monthly intravitreal injections of THR-317 and ranibizumab in subjects with center-involved DME. The combination of ranibizumab and sham was used as a control. A total of 70 patients were enrolled in the study (NCT03499223).

In this exploratory proof of concept study, the efficacy of the combination therapy in terms of the patient's Best Corrected Visual Acuity (BCVA) was assessed as primary endpoint.

At Month 3, no improvement was observed in mean BCVA with the combination therapy when compared to ranibizumab monotherapy in the overall population. As measured by the Early Treatment of Diabetic Retinopathy Study (*ETDRS*) standardized eye chart, the combination therapy achieved an increase of 8.71 Letters versus an increase of 8.18 Letters for the monotherapy arm.

The combination therapy did show a certain improvement at Month 3 in mean BCVA in two pre-specified patient sub-groups:

- In patients with poor (or no) response to prior anti-VEGF, a mean increase of 8.08 Letters was observed for the combination therapy vs 6.43 Letters increase for ranibizumab monotherapy
- In patients with Baseline BCVA \leq 65 letters a mean increase of 11.14 Letters was observed for the combination therapy vs 8.88 Letters increase for ranibizumab monotherapy

Topline data from the Phase 2 study show that THR-317 in combination with ranibizumab, is safe and well tolerated. No drug-related ocular serious adverse events were reported in the study.

Patrik De Haes, M.D., CEO of Oxurion, says: *“The topline results from this exploratory Phase 2 study indicate that THR-317 in combination with ranibizumab could play a role in the treatment of poor (or no) response to prior anti-VEGF and with patients with a baseline BCVA of less or equal to 65 letters. We will continue to review and analyze these data before deciding on how to best position this program as we progress our clinical-stage portfolio of next-generation therapies 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 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-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
- 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

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.