

Oxurion NV Reports Positive Topline Data from Phase 1 study evaluating THR-687 for treatment of DME

THR-687 is a potent pan-RGD integrin antagonist in development for DME and DR

- Topline data show that THR-687 is well-tolerated and safe. No dose-limiting toxicities or serious adverse events reported
- Rapid onset of action and prolonged effect on Best Corrected Visual Acuity (BCVA) seen across all doses of THR-687 following a single injection
 - Mean BCVA improvement of 3.1 letters at Day 1
 - Mean BCVA improvement of 9.2 letters at Month 1
 - Mean BCVA improvement of 8.3 letters at Month 3
- A dose response effect in BCVA and Central Subfield Thickness (CST) was shown
- Phase 2 study planned for H2 2020 with this VEGF-independent treatment option in the treatment of naïve DME patients

Leuven, Belgium , 7 January 2020 – 07.00 AM CET – [Oxurion NV](#) (Euronext Brussels: OXUR), a biopharmaceutical company developing a pipeline of novel clinical drug candidates acting on VEGF-independent pathways to preserve vision in patients with diabetic eye disease, today reports positive topline data from a Phase 1 study with THR-687, a novel, potent, pan-RGD integrin antagonist for the treatment of Diabetic Macular Edema (DME).

The Phase 1, open-label, multi-center (US), single dose escalation study evaluated the safety of a single intravitreal injection of 3 increasing doses (0.4 mg, 1.0 mg, 2.5 mg) of THR-687 for the treatment of DME (NCT03666923). Patients recruited into the study had a history of response to prior anti-VEGF and/or corticosteroid treatment. At baseline, the study patient population had a mean BCVA of 56 letters, and a mean Central Subfield Thickness (CST) of 542µm.

Topline data from the trial show that THR-687 is well-tolerated and safe with no dose-limiting toxicities. No serious adverse events were reported at any of the doses evaluated in the study.

The study also looked at efficacy including changes to the patient's BCVA. Across all doses, a rapid onset of action in mean BCVA was observed from Day 1 with an increase of 3.1 letters, which further improved to 9.2 letters at Month 1. This activity was maintained with a mean BCVA improvement of 8.3 letters at Month 3 following a single injection of THR-687.

A clear dose response was seen with the greatest positive effect on BCVA and Central Subfield Thickness (CST) with the highest dose of THR-687. For this highest dose, a mean BCVA Improvement of 11 letters was noted at Day 14, with a peak improvement of 12.5 letters at Month 3. Similarly, a peak mean CST decrease of 106 µm was observed at Day 14 with the highest dose of THR-687.

Oxurion is currently preparing the complete data analysis from this Phase 1 study with THR-687 and plans to present further clinical data at the Angiogenesis, Exudation, and Degeneration 2020 Meeting on 8th February in Miami, Florida.

THR-687 is the second VEGF-independent clinical candidate under development for diabetic eye disease by Oxurion. THR-149, the Company's other and most advanced VEGF-independent treatment also delivered positive Phase 1 results in July 2019.

Arshad Khanani, M.D., M.A., Director of Clinical Research at Sierra Eye Associates, Reno, Nev, and clinical investigator in this study, commenting on the results said, *“The topline data from this Phase 1 study show that THR-687 is safe and well tolerated at all of the dose levels tested. I am very encouraged to see excellent signs of efficacy so quickly post treatment. We also noticed a durability of effect to the patient’s vision as measured by BCVA following just one single injection of THR-687. This promising initial data indicate that THR-687 could have the potential of being an effective monotherapy for patients with DME.”*

Patrik De Haes, M.D., CEO of Oxurion, said: *“We are delighted by these encouraging topline data, which confirm that our Integrin Antagonist THR-687 is not only well-tolerated and safe for intravitreal use, but could be effective in inducing a rapid and sustained gain in BCVA in patients with DME. We are also pleased to see a clinically meaningful reduction in mean CST with our highest dose in this patient population, following just one single injection. These very encouraging findings provide us with the information needed to design the planned Phase 2 clinical study with THR-687. This study in treatment naïve DME patients is due to start later this year. Following the positive data from a Phase 1 with our Plasma Kallikrein Inhibitor THR-149 for DME, we expect to have two potential best-in-class compounds with a distinct profile targeting two validated VEGF-independent pathways entering a Phase II clinical study in 2020.”*

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing a pipeline of novel clinical drug candidates acting on VEGF-independent pathways to preserve vision in patients with diabetic eye disease, a leading cause of blindness in people of working age worldwide.

Oxurion’s clinical 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-149 was developed in conjunction with Bicycle Therapeutics plc (NASDAQ:BCYC)
- THR-687, a pan-RGD integrin antagonist, that has shown positive topline Phase 1 results for the treatment of DME. A Phase 2 is expected to start in H2 2020. THR-687 is an optimized compound derived from a broader library of integrin antagonists 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.