

Oxurion Provides Update on Clinical Pipeline Progress

Completed Patient Enrollment for Part A of Phase 2 INTEGRAL Trial Evaluating THR-687 for treatment of Diabetic Macular Edema (DME) in treatment naïve subjects

US IRB Approval of Protocol Amendment to Part B of the Phase 2 KALAHARI Trial Assessing THR-149 versus aflibercept for treatment of DME in patients that suboptimally respond to anti-VEGF therapy

Full dataset from Part A of KALAHARI Trial to be presented at Angiogenesis on February 12th

Leuven, BELGIUM, Boston, MA, US – 7 January 2022 – 7.00 AM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard of care ophthalmic therapies, with a clinical stage portfolio in vascular retinal disorders, today announced updates on its two clinical programs, THR-687, initially being developed for first line treatment of DME, and THR-149 being developed for second line treatment of DME.

THR-687 – Completed Patient Enrollment for Part A of the Phase 2 Clinical Trial (“INTEGRAL”) Evaluating THR-687 in Patients with DME

THR-687 is a potential best-in-class small molecule pan-RGD integrin antagonist being developed for the treatment of DME and holding promise for the treatment of wet Age-related Macular Degeneration (wAMD) and macular edema following Retinal Vein Occlusion (RVO). The INTEGRAL trial is a two-part Phase 2, randomized, multi-center clinical trial and is the first trial in which multiple intravitreal injections of THR-687 will be administered in humans.

“We are pleased to announce the completion of patient enrollment for Part A of the Phase 2 INTEGRAL trial of THR-687,” Tom Graney, CFA, Chief Executive Officer of Oxurion commented. “The rapid enrollment in this trial is a testament to how interested physicians and patients are to have a new mechanism of action with the potential to offer improved efficacy over the standard of care anti-VEGF therapy. This milestone brings us closer to delivering a potential first line treatment of choice for patients with DME. With its unique mechanism of action, THR-687 demonstrated promising results in its Phase 1 study, which showed an encouraging efficacy signal following just a single dose. This best-in-class small molecule has further potential to be developed to raise the standard of care in additional significant indications, including wAMD and RVO.”

Part A of the trial will assess two dose levels of multiple THR-687 injections and, if successful, the trial’s results will be used to select the appropriate dose for Part B of the INTEGRAL trial that will evaluate the efficacy and safety of THR-687 versus aflibercept (the current standard of care) for the treatment of DME. Part B of the trial will include both treatment experienced and treatment naïve subjects.

The dose selection decision, following Part A, is anticipated in the first half of 2022 with top line data from Part B expected in the second half of 2023.

THR-149 – Received Approval from the US Institutional Review Board (IRB) to Amend the Protocol for Part B of the Phase 2 Clinical Trial (“KALAHARI”) Assessing THR-149 versus aflibercept for Treatment of DME

THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy.

The trial’s U.S. IRB has approved a protocol amendment to Part B of its ongoing KALAHARI trial assessing multiple doses of THR-149 versus aflibercept for the treatment of DME. The changes to the protocol are designed to:

- Enhance the probability of a successful trial outcome without impacting the trial timelines by refining the patient inclusion/exclusion criteria, and
- Provide preliminary data on the use of THR-149 before, or immediately following, anti-VEGF therapy by exploring synergies of THR-149 with aflibercept utilizing a cross-over style design with a fourth injection at month four

In September 2021, Oxurion announced positive data from Part A of the Phase 2 KALAHARI trial evaluating THR-149 for the treatment of DME. These data demonstrated that THR-149 had a favorable safety profile, with no serious adverse events or inflammation observed at any dose level. The high dose achieved a mean improvement in Best Corrected Vision (BCVA) of 6.1 letters at Month 3 without the need for rescue medication. BCVA is the primary endpoint for registration in DME trials.

The post-hoc analysis of the Part A results identified opportunities to optimize the inclusion and exclusion criteria for Part B for both probability of success and speed. Part B of the KALAHARI trial is ongoing, assessing three monthly injections of THR-149, compared to three monthly injections of aflibercept, up to Month 3. As from Month 3, the safety and efficacy of a switched fourth injection (THR-149 to aflibercept or aflibercept to THR-149) will be evaluated in about half of the subjects whereas in the other half of the subjects the durability of three monthly injections (THR-149 or aflibercept) will be evaluated through a single sham injection. The trial is planned to randomize approximately 108 subjects in Part B and the primary endpoint remains the mean change in BCVA letter score from baseline, at Month 3.

Tom Graney, CFA, Chief Executive Officer of Oxurion, said, “I am pleased that the IRB has approved our protocol amendments to Part B of the Phase 2 KALAHARI trial. These amendments, including refining the patient inclusion and exclusion criteria, have been made based on further post-hoc analyses of the data from Part A of the trial, which have improved our understanding of which patients are most likely to respond to treatment with THR-149. We believe these changes will maximize our ability to achieve a successful trial outcome while preserving the benefits of the initial trial design and maintaining our timelines.”

Additional new data from Part A from the KALAHARI trial will be presented at Angiogenesis, Exudation, and Degeneration 2022, a virtual conference taking place February 11 and 12, 2022. Arshad M. Khanani, M.D., M.A., Director of Clinical Research at Sierra Eye Associates, Reno, Nevada, US will present the Part A data on February 12th.

Final topline results from Part B the KALAHARI trial are expected by mid-2023.

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard of care ophthalmic therapies, which are designed to better preserve vision in patients with retinal vascular disorders including diabetic macular edema (DME), the leading cause of vision loss in diabetic patients worldwide as well as other conditions, including wet age-related macular degeneration (wAMD) and retinal vein occlusion (RVO).

Oxurion is aiming to build a leading global franchise in the treatment of retinal vascular disorders based on the successful development of its two novel therapeutics:

- THR-687 is a highly selective pan-RGD integrin antagonist that is initially being developed as a potential first line therapy for DME patients. Positive topline results in a Phase 1 clinical study assessing THR-687 as a treatment for DME were announced in 2020. Oxurion is currently conducting a Phase 2 clinical trial (“INTEGRAL”) evaluating THR-687 in patients with DME. THR-687 also has the potential to deliver improved treatment outcomes for patients with wAMD and RVO.
- THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy. THR-149 has shown positive topline Phase 1 results for the treatment of DME. The company is currently conducting a Phase 2 clinical trial (“KALAHARI”) evaluating multiple injections of THR-149 in DME patients previously showing a suboptimal response to anti-VEGF therapy. Following positive data from Part A of this Phase 2 trial (dose selection), the Company has initiated Part B of the trial.

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.