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PRESS RELEASE

Regulated Information – Inside Information

OXURION Announces Positive Results from Part A of Phase 2 Study Evaluating THR-149 for Treatment of Diabetic Macular Edema (DME)

Decision taken to move the highest dose of THR-149 (0.13mg) into Part B of the study based on favorable safety profile and positive efficacy data

Oxurion is moving into Part B of study evaluating THR-149 against aflibercept

THR-149 is a potent plasma kallikrein inhibitor for the treatment of the 40-50% of DME patients who respond suboptimally to anti-VEGF therapy

Leuven, BE, Boston, MA, US – September 30, 2021 – 07.00 AM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard of care ophthalmic therapies, today announced positive data from Part A of its Phase 2 study ("KALAHARI") of THR-149, a plasma kallikrein inhibitor, for the treatment of DME. Based on these data the Company has decided to move the highest dose of THR-149 (0.13mg) into Part B of the study, which is expected to begin shortly.

THR-149, is being developed as a potential new standard of care intravitreal (IVT) therapy for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy. THR-149 acts through inhibition of the plasma kallikrein-kinin (PKaI-Kinin) system, a validated VEGF-independent target for DME.

Arshad M. Khanani, M.D., M.A., Director of Clinical Research at Sierra Eye Associates, Reno, Nevada, US, comments: *"I am excited to see the results from Part A of the KALAHARI study, which was conducted in patients who have shown suboptimal response to anti-VEGF therapy. These patients currently have limited treatment options, and the mean BCVA gains of + 6.1 letters at 3 months with stable CST in patients treated with the highest dose of THR-149 is encouraging. I am looking forward to recruiting patients into Part B of this trial. I am hopeful that the KALAHARI study will demonstrate that THR-149 could benefit the 40-50% of DME patients who respond suboptimally to anti-VEGFs."*

The Phase 2 KALAHARI study is a two-part, randomized, prospective, multi-center study assessing multiple injections of THR-149 in DME patients who have previously shown a suboptimal response to anti-VEGF therapy. The endpoints of Part A of the study were safety (n= 23) and efficacy (n = 20).

In Part A of the study, three dose levels of THR-149 (0.005mg, 0.022mg and 0.13mg), each administered in three monthly IVT injections, were evaluated in order to select the best dose for Part B of the study.

Results from Part A showed that all dose levels of THR-149 had a favorable safety profile, with no serious adverse events being observed. All adverse events in the study eye were mild to moderate in intensity and no severe ocular adverse events were reported.

Finally, no inflammation was seen in the study eye of any patient at any dose evaluated in Part A of the study.

When assessing efficacy, three IVT injections of THR-149 (0.13mg) delivered the most promising results in terms of Best Corrected Visual Accuity (BCVA), the primary endpoint for registration in DME, and also delivered a stable Central Subfield Thickness (CST), a promising result in a population were if left untreated CST would be expected to deteriorate.

- No patients in the high dose group (n = 8) required rescue medication.
- In terms of BCVA, the highest dose delivered a mean 6.1 letter improvement at Month 3. The range of BCVA changes with the highest dose was -0.4 to 12.6 letters at Month 3.
- In terms of CST, the highest dose showed a stable CST (mean change of 13 µm) at Month 3. The range of CST changes with the highest dose was -37.1 to 63.6 µm at Month 3.

Oxurion intends to present a more complete data set from Part A of the KALAHARI study at an upcoming leading ophthalmology conference.

Based on these data, the Company will shortly start Part B of the study which will enroll just over one hundred patients who have previously shown a suboptimal response to anti-VEGF therapy, and where THR-149 will be evaluated against aflibercept, the current standard of care, as the active comparator.

Final topline results from the KALAHARI study are expected by mid-2023.

Tom Graney, CFA, Chief Executive Officer of Oxurion, comments, "*The positive data from Part A of the KALAHARI study provides proof of concept for multiple injections of THR-149 in this important DME patient population and is a significant de-risking event for the Company. We are pleased to be able to proceed into the second part of the study, where we hope to confirm THR-149's ability to address the significant unmet need in this patient population that experiences a suboptimal response to anti-VEGFs and currently lacks adequate treatment options. I would like to thank the patients, physicians, and the clinical teams for their support in completing Part A of this important study. These very encouraging results with THR-149, alongside the initiation of our Phase 2 ("INTEGRAL") study with THR-687, a pan-RGD integrin antagonist, being developed as a potential first line therapy for DME patients, gives Oxurion one of the most exciting pipelines in ophthalmology today."*

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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 (AMD) 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 wet AMD 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 study (dose selection), the Company has initiated Part B of the study.

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.