Oxurion NV - Publication of Positive Phase 1 Clinical Data evaluating THR-687 for Treatment of DME in Ophthalmology Science, the American Academy of Ophthalmology Journal

THR-687 is a potent pan-RGD integrin antagonist holding potential as next generation first line therapy for DME, wet AMD and RVO

Phase 2 Clinical Study THR-687 in DME currently recruiting patients

Leuven, BE, Boston, MA, US – August 17, 2021 – 08.00 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, announces that the positive Phase 1 study of THR-687, a novel, highly potent integrin agonist for the treatment of DME has just been published in Ophthalmology Science, the journal of the American Academy of Ophthalmology.

The multicenter, dose escalation study was designed to evaluate the safety and preliminary efficacy of three dose levels of THR-687 (0.4, 1.0 or 2.5mg) in subjects with center-involved DME following a single intravitreal injection.

As reported from the top line data in 2020, a single injection of THR-687 was safe and well tolerated, showing a very encouraging efficacy signal as measured by a rapid gain in BCVA with three months durability and a decrease in CST up to one month following the injection.

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.

THR-687 will next be investigated in the INTEGRAL Phase 2 study, a randomized, multicenter trial in DME. This is the first trial in which multiple intravitreal injections of THR-687 will be administered in humans. The two-part study will assess different dose levels of multiple THR-687 injections (Part A) and then go on to evaluate the efficacy and safety of the selected dose of THR-687 versus aflibercept (the current standard of care) for the treatment of DME (Part B).

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

Tom Graney, CFA, CEO of Oxurion comments, "*I am pleased that the significance of the Phase 1 THR-687 data has been recognised by its publication in the prestigious American Academy of Ophthalmology journal. The highly promising results from just a single dose of THR-687 have warranted the planning of the Phase 2 study which just opened enrolment of patients. There remains a significant unmet medical need in DME and THR-687 has the potential to be a transformative first line therapy for the many patients suffering from this serious condition. We would like to thank the patients for their participation in the Phase 1 study as well as the world-class investigators that worked on the trial and the publication.*"

Beyond DME, THR-687 has the potential to be developed for additional vascular retinal disorders including for wet Age-related Macular Degeneration (wet AMD) and retinal vein occlusion (RVO). These additional indications, alongside DME, mean that THR-687, is targeting a total market opportunity estimated to be worth $12+ billion annually.

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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 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 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 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 evaluating multiple injections of THR-149 in DME patients previously showing suboptimal response to anti-VEGF therapy. Dose selection data from Part A of the study, which is fully enrolled, is expected in the second half of 2021.

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.