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PRESS RELEASE

Regulated Information

Oxurion NV Business Update – Q3 2020

Progressing Clinical Development of Next Generation Diabetic Macular Edema (DME) Therapies – Beyond anti-VEGF

First Patient dosed in Phase 2 study ('KALAHARI') evaluating THR-149, a potent plasma kallikrein inhibitor, for the treatment of DME

Tom Graney, CFA, former Vertex and Generation Bio CFO, appointed Chief Financial Officer

Grace Chang, M.D., Ph.D. appointed Chief Medical Officer

Highlights

- First patient dosed in Phase 2 study ('KALAHARI') evaluating multiple injections of THR-149, a potent plasma kallikrein inhibitor, for the treatment of DME in September
- Tom Graney, CFA, former Vertex and Generation Bio CFO, appointed as Chief Financial Officer to Oxurion bringing significant operational, US capital markets and investor relations expertise
- Grace Chang, M.D., Ph.D. appointed as Chief Medical Officer to lead the company's clinical programs for THR-149 and THR-687
- Planning for a Phase 2 DME study with THR-687 a pan-RGD integrin antagonist ongoing, following positive Phase 1 data study released in January

Financial

- At the end of September 2020, Oxurion had cash, cash equivalents & investments of €31.6 million. This compares to €52.9 million at the end of December 2019.

Virtual R&D Day

Oxurion Virtual R&D Day –- **today October 15, 2020 at 5.30 PM CET/ 4.30 PM BST/ 11.30 AM ET**, featuring Ramin Tadayoni, M.D., Ph.D. and Arshad Khanani, M.D., M.A. providing expert views on THR-149 and THR-687 clinical data and programs (please see below for details of how to join the meeting).

Leuven, Belgium, Boston, MA, US - October 15, 2020 – 8.00 AM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard-of-care ophthalmic therapies, with a focus on diabetic macular edema (DME), today issues its business and financial update for the period ending September 30, 2020.

Oxurion is focused on developing an industry leading DME franchise based on novel therapies designed to potentially provide improved visual outcomes for DME patients, independent of anti-VEGF. DME is a significant global healthcare problem and the major cause of vision loss in diabetic patients worldwide.

The prevalence of DME was estimated to be 2.8 million people in the US, EU5 and Japan in 2019. The current market value for DME treatments in these markets has been estimated to be approximately $4.5 billion.

The Company is progressing its pipeline of innovative clinical drug candidates for treating DME. Oxurion's clinical development pipeline consists of two novel products with different and complimentary, non-VEGF, modes of action:

> **THR-149** is a potent plasma kallikrein inhibitor with the potential to become the treatment of choice for DME patients who respond sub-optimally to anti-VEGF therapy.
>
> **THR-687** is a potential best in class small molecule pan-RGD integrin antagonist being developed to treat DME with the possibility to become the standard of care for all treatment-naïve DME patients.

Patrik De Haes, M.D., CEO of Oxurion, commented:

"We have made significant progress in developing our DME franchise in the last eighteen months.

We have recently started our Phase 2 study of THR-149 in patients with DME. This two-part study will first select the optimal dosing regimen of THR-149 and will then compare this in a multiple dosing regimen with aflibercept in terms of the improvements in best corrected visual acuity that it can deliver. This Phase 2 data is designed to support our plans to position THR-149 as the treatment of choice for the large number of DME patients who have a sub-optimal response to anti-VEGF therapy.

In January we announced positive and highly promising Phase 1 results with THR-687 which further strengthened our confidence that this novel pan-RGD integrin antagonist could deliver improved visual outcomes to a broad population of DME patients when compared to anti-VEGFs, the current standard of care. We are currently carrying out additional multiple dose preclinical studies to support an IND (Investigation New Drug Application) as part of our plan to start a Phase 2 study in mid-2021.
I am also pleased to welcome to our senior management team Grace Chang as our new Chief Medical Officer and Tom Graney as Chief Financial Officer. Their experience and expertise will be great assets to the company, and I am confident they will make important contributions to Oxurion's future development. With both Tom and Grace being based in the US, we are starting to build the transatlantic organization we need to deliver on our global ambition.

We believe we are well positioned to build the industry's leading DME franchise, based on successfully developing THR-149 and THR-687, two novel and complimentary drug candidates that could offer improved therapeutic options beyond anti-VGEFs. We are convinced that this focused strategy will deliver significant benefits to DME patients globally as well as value to our shareholders."

Key Management Appointments

Tom Graney, CFA, appointed Chief Financial Officer

In October, Oxurion announced the appointment of Tom Graney, CFA as its Chief Financial Officer (CFO). Mr. Graney began his role on 14th October and will be based in Boston, MA, US. He succeeds Dominique Vanfleteren who, according to plan, is leaving Oxurion to pursue other interests.

Tom has over 25 years' experience in senior finance, strategy and operational roles including capital raising, accounting, and audit. He most recently served as CFO at Generation Bio (NASDAQ: GBIO), a non-viral gene therapy company based in Cambridge, MA, where he led all of the company's financial operations.

Prior to joining Generation Bio, Tom was Senior Vice President (SVP) and CFO at Vertex Pharmaceuticals (NASDAQ: VRTX), one of the world's most highly valued biotech companies, with a multi-billion-dollar turnover. At Vertex Tom was responsible for financial strategy and operations including finance, accounting, and internal audit functions.

Prior to Vertex, he was the CFO and senior vice president, finance, and corporate strategy at Ironwood Pharmaceuticals (NASDAQ: IRWD), a GI-focused healthcare

company. Before joining Ironwood, Tom spent 20 years with Johnson & Johnson, serving in various roles in the US and abroad, including being Worldwide VP of Finance and CFO of Ethicon, a major medical device company and VP and CFO of Janssen Pharmaceuticals NA, a major pharmaceutical company in North America.

Grace Chang, M.D., Ph.D. appointed Chief Medical Officer

In August, Oxurion appointed Grace Chang, M.D., Ph.D. as its Chief Medical Officer (effective August 1, 2020). She will be responsible for leading the Company's clinical programs for both THR-687 and THR-149 as Oxurion looks to build a world-leading DME franchise that could provide much improved therapeutic solutions for all DME patients.

Dr Chang is a board-certified ophthalmologist and practicing vitreoretinal surgeon with deep expertise in ophthalmic drug research and development.

Dr Chang is currently an adjunct Clinical Associate Professor in the Department of Ophthalmology, Vitreoretinal Service at the University of Southern California in Los Angeles.

Diabetic Macular Edema – Oxurion's key focus

Diabetic macular edema (DME) is a result of diabetes caused by fluid accumulation in the macula (central part of the retina), due to leaking blood vessels, leading to swelling of the macular area due to the increased permeability of the vessels.

DME is caused by another complication of diabetes, called diabetic retinopathy (DR), in which blood vessels in the eye are damaged, allowing fluid to escape. DR is the presence and characteristic evolution of typical retinal microvascular lesions in an individual with diabetes. DR is a chronic, progressive, sight-threatening, and life-altering disease, and is the leading cause of vision loss in working-age adults (20-65 years). DME can occur at any stage in the development of DR.

DR and DME are a growing public health concern due to the rapid growth in the number of people with diabetes globally. More than one in three people living with diabetes will develop some form of DR in their lifetime, and a third of those will have some vision-threatening form of the disease such as DME.

An estimated 37.8 million people have been diagnosed with diabetes in the United States (US), European top five countries (EU5) (France, Germany, Italy, Spain, and the United Kingdom), and Japan. If the undiagnosed population is included, the estimated number of people with diabetes in these countries increases to 61.3 million people.

The prevalence of DME was estimated to be 2.8 million people in the US, EU5 and Japan in 2019. The current market value for DME treatments in these markets has been estimated to be approximately $4.5 billion.

The market for DME therapies is dominated by anti-VEGFs, which are the current standard of care. However, anti-VEGFs have been shown to deliver sub-optimal results in a significant portion of the patient population. Around 40% of DME patients have an unsatisfactory early visual response with anti-VEGF therapy, and in many cases anti-VEGFs fail to achieve a clinically meaningful visual improvement.

Oxurion is focused on solving these unmet medical needs in DME.

Oxurion's Emerging DME Franchise

In general, the treatment of DME is centered around anti-VEGF therapies. However, despite the significant success of anti-VEGFs, there will always be a need from both physicians and patients for improved therapies that have:

- Treatment capabilities for the 40% of DME patients who respond sub-optimally to anti-VGEFs
- Faster onset of action
- Better therapeutic effect in terms of visual function, best corrected visual acuity (BCVA), and response rate (proportion of patients)
- Longer duration of response allowing extended treatment intervals
- Improved convenience of treatment through a simpler dosing regimen

Those requirements are driving the development of THR-149 and THR-687 to meet specific unmet needs in the market so that these novel compounds could become the new standard of care for patients with DME. Oxurion's emerging DME franchise will be based on the successful development of THR-149 and THR-687, two novel therapeutics with different modes of action designed for specific complementary target patient groups.

Oxurion is confident that with both THR-149 and THR-687 it will be able to provide new tailored therapeutic solutions that deliver improved clinical outcomes to most DME patients.

Oxurion's DME Pipeline

THR-149 – a plasma kallikrein inhibitor for treatment of DME: First Patient Treated in Phase 2

The first patient has been treated in the Phase 2 study evaluating THR-149 for treatment of DME.

THR-149 is a novel plasma kallikrein inhibitor being developed as a potential new standard of care for the 40% of DME patients who respond sub-optimally to anti-VEGF therapy.

THR-149 acts through inhibition of the Plasma Kallikrein-Kinin (PKaI-Kinin) system, a validated target for DME.

THR-149 is currently in a 2-part Phase 2 development program, called the 'KALAHARI' study.

The first part (Part A) will evaluate 3 dose levels of multiple injections of THR-149 in patients with DME to select the optimal dosing regimen. Initial data (from Part A) is expected in mid-2021.

In Part B of the study, the dosing regimen selected in Part A will be compared to the current anti-VEGF standard of care in the form of aflibercept (Eylea) in terms of its ability to improve BCVA.

A positive Phase 1 study with THR-149 showed that it:

- Is well-tolerated and safe. No dose-limiting toxicities nor drug-related serious adverse events were reported at any of the dosages evaluated in the study.
- Delivered promising results in relation to efficacy, particularly improvements in the patient's BCVA. A rapid onset of action was observed from Day 1, with an increasing average improvement in BCVA of up to 7.5 letters at Day 14.
- Importantly, this activity was maintained with an average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149.

This novel drug candidate was generated using Bicycle Therapeutics' Bicycles® technology platform.

THR-687 - a small molecule pan-RGD integrin antagonist for the treatment of DME

Positive Phase 1 Results with THR-687 for the treatment of DME – Phase 2 program planned to start in mid-2021

Oxurion is developing THR-687, a potential best in class pan-RGD integrin antagonist, to preserve vision in a broad range of patients with DME.

Topline data from the Phase 1 trial showed 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 as measured by mean BCVA change 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 in terms of BCVA with the highest dose of THR-687 delivering a mean BCVA Improvement of 11 letters at Day 14, with a peak improvement of 12.5 letters at Month 3.
- In addition, a peak mean central subfield thickness (CST) decrease of 106 µm was observed at Day 14 with the highest dose of THR-687.

Data from this positive Phase 1 study with THR-687 were presented by a leading retina expert at the Bascom Palmer Eye Institute Angiogenesis, Exudation, and Degeneration 2020 Meeting in February 2020 in Miami (US).

Oxurion is preparing a Phase 2 study with THR-687 that is expected to start by mid-2021. The team is currently carrying out additional multiple dose pre-clinical studies to complete the IND (Investigation New Drug Application) submission ahead of the planned start of a Phase 2 study in mid-2021.

Oxurion presented new pre-clinical data on THR-687 at the recent EURETINA 2020 Virtual Meeting October 2-4th. The European Society of Retina Specialists (EURETINA) was established over 20 years ago and hosts the leading annual European retinal congress which now attracts over 5,000 vitreoretinal and macular specialists.

Company senior scientists delivered two pre-clinical data presentations at the meeting.

The first presentation (title: THR-687, a potent pan-RGD integrin antagonist, holds promise as next-generation therapy for diabetic macular edema) confirmed THR-687 as a promising drug candidate for the treatment of vision-threatening retinal pathologies such as diabetic retinopathy (DR) and DME. The second (title: Characterization of the acute rat model of sodium iodate-induced dry age-related macular degeneration) reported data from a new preclinical model for testing and validation of drug candidates for different stages of dry AMD using complementary read-outs.

Details of the abstracts can be found on the EURETINA 2020 Virtual website:
https://www.euretina.org/congress/amsterdam-2020/virtual-2020-freepapers/

Financial Update

As of September 30, 2020, Oxurion had €31.6 million in cash, cash equivalents and investments. This compared to €52.9 million as of the end of December 2019.

Oxurion Virtual R&D Day

Thursday, October 15, 2020 at 5.30pm CET/ 4.30pm BST/ 11.30am ET

Oxurion (Euronext Brussels: OXUR) highlighting innovative drug candidates for next generation DME therapy, with expert views on THR-149 (Plasma Kallikrein inhibitor) and THR-687 (pan-RGD integrin antagonist) clinical data and ongoing and future clinical development strategies, featuring:

> **Ramin Tadayoni, M.D., Ph.D.,** *Professor of ophthalmology at University of Paris, Head of the Ophthalmology Departments at Lariboisière, St Louis and Rothschild Foundation Hospitals in Paris, France,*
>
> **Arshad Khanani, M.D., M.A.,** *Managing Partner, Director of Clinical Research, Director of Fellowship at Sierra Eye Associates, and Clinical Associate Professor at the University of Nevada, Reno, US.*

Conference call participant numbers:

Brussels: +32 (0) 2 789 8603

Belgium Toll Free: 0800 746 68

Standard International Access: +44 (0) 20 3003 2666

UK Toll Free: 0808 109 0700

USA Toll Free: 1 866 966 5335

Password: Oxurion

Please consult the underneath link for webcast registration:

https://www.investis-live.com/oxurion/5f7c2e6ed33b270c005a4f88/ffdl

An on-demand version of the event will also be made available shortly after the event has finished, this will be accessible via the same link.

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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 diabetic macular edema (DME), the leading cause of vision loss in diabetic patients worldwide.

Oxurion is aiming to build the leading global franchise in the treatment of DME, based on the successful development of its two novel therapeutics:

- THR-149, a plasma kallikrein inhibitor being developed as a potential new standard of care for DME patients who respond sub-optimally 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 with DME-patients who previously responded sub-optimally to anti-VEGF therapy. THR-149 was developed in conjunction with Bicycle Therapeutics PLC (NASDAQ: BCYC)

- THR-687 is a pan-RGD integrin inhibitor, that is initially being developed as a potential new standard of care for all DME patients.

  Positive topline results in a Phase 1 clinical study assessing THR-687 as a treatment for DME were announced in January 2020. THR-687 is expected to enter a Phase 2 clinical trial by mid-2021 after receiving regulatory approval. THR-687 is an optimized compound derived from a broader library of integrin inhibitors 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 US. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable US state securities laws.