Oxurion NV : Oxurion NV Business Update - Q1 2019

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Significant Progress with Novel Clinical Diabetic Eye Disease Portfolio

Enrollment of THR-317 Phase 2 Combination Study & THR-149 Phase 1 Study Completed Ahead of Schedule

First Clinical Readout Expected by Q3 2019

Total Cash & Investments at €76.2 million on 31 March 2019

Highlights

- Patient enrollment completed in April 2019 of a Phase 2 trial evaluating the efficacy and safety of intravitreal THR-317 (anti-PlGF) administered in combination with ranibizumab (anti-VEGF) for the treatment of diabetic macular edema (DME)
- Patient enrollment completed in April 2019 of a Phase 1 dose escalation safety study evaluating THR-149 for the treatment of DME
- Results from THR-317 and THR-149 clinical studies are expected by Q3 2019
- Two further clinical read-outs expected before end of 2019
- Oxurion had €76.2 million in cash & investments at the end of March 2019. This compares to €85.1 million at the end of December 2018.

Leuven, Belgium, May 8, 2019 - Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing innovative treatments to preserve vision in patients with diabetic eye disease, today issues a business update and a financial update for the three-months ending March 31, 2019.

Oxurion is developing a competitive pipeline of disease modifying drug candidates for diabetic eye disease, particularly DME.

The Oxurion clinical development pipeline consists of novel products with different modes of action, which, together potentially give the Company access to a significant share of the diabetic eye disease market. Oxurion's clinical pipeline comprises of:

- a human placental growth factor (PlGF) neutralizing monoclonal antibody **(THR-317)** which is in a Phase 2 study evaluating the efficacy and safety of intravitreal THR-317 when administered in combination with ranibizumab (Lucentis®), for the treatment of DME. Recruitment of this study is completed, and results are expected in early Q3 2019.

In addition, THR-317 is being evaluated in a Phase 2 study for the treatment of Idiopathic Macular Telangiectasia Type 1 (MacTel 1), a rare disease that affects the macula and can lead to vision loss. First data from this study are expected towards the end of 2019.

- a potent plasma kallikrein inhibitor **(THR-149)** is in a Phase 1 multicenter, dose escalation study for the treatment of DME. Recruitment of this study has recently completed with results anticipated by early Q3 2019.

- a small molecule pan-RGD integrin antagonist **(THR-687)** being developed to treat a broad range of patients with diabetic eye disease. THR-687 entered the clinic in September 2018. Results from the on-going Phase 1 study are expected towards the end of 2019.

Patrik De Haes, MD, CEO of Oxurion nv, commented**:** *"We are making excellent progress with our competitive pipeline of disease-modifying drug candidates for diabetic eye disease, the leading cause of blindness in people of working age. We have completed recruitment ahead of schedule of our Phase 2 study evaluating the efficacy and safety of intravitreal THR-317 when administered in combination with ranibizumab (Lucentis®), for the treatment of DME. We have also completed recruitment of our Phase I study with THR-149. Results from these studies are expected by Q3 2019. Later in the year we plan to announce the results from a Phase I study with THR-687 and a Phase 2 study with THR-317 in patients with MacTel1. We are confident that 2019 will be a milestone year for Oxurion as we continue to advance our clinical pipeline of novel disease-modifying therapies and remain confident in their potential to preserve the vision of patients with diabetic eye disease."*

Diabetic Eye Disease - A Significant and Growing area off medical need

Diabetes is a major global healthcare problem with an estimated 425 million adults living with diabetes worldwide today. This number is expected to increase to over 625 million by 2045, according to the International Diabetes Federation.

Diabetic eye disease is caused by hyperglycemia (high blood glucose levels) associated with diabetes. If left unchecked hyperglycemia causes damage to the capillaries supplying blood and hence oxygen to the retina, the structure at the back of the eye responsible for vison.

Diabetic retinopathy (DR) is a serious, sight-threatening disease and the leading cause of vision loss among working-age adults. DR progresses from mild, non-proliferative to more severe or even proliferative stages. It is estimated that there are 150 million diabetics with DR of which 50 million have vision threatening disease.

Diabetic macular edema (DME) is a severe complication of DR. DME is an accumulation of fluid in the macula - the part of the retina that controls detailed vision - due to leaking blood vessels. DME represents an area of major unmet medical need. The current standard of care, anti-VEGFs, have shown to deliver sub-optimal results, with more than 50% of patients having an unsatisfactory early visual response with anti-VEGF therapy, and many of cases failing to achieve a clinically meaningful visual improvement over time.

Oxurion Clinical and Pre-clinical Development Update

THR-317 - a Humanized mAb Against Human PlGF for the treatment of DME

THR-317 (anti-PlGF) is a recombinant humanized monoclonal antibody directed against the receptor-binding site of human placental growth factor (PlGF) being developed for the treatment of DME. In pre-clinical models, anti-PlGF has been shown, in addition to anti-angiogenic and anti-edema properties, to be anti-inflammatory.

Phase 2 Clinical study evaluating THR-317 in combination with ranibizumab (Lucentis®), an anti-VEGF

In April 2019, enrollment was completed, ahead of schedule, for the Phase 2 study evaluating the efficacy and safety of intravitreal THR-317 administered in combination with ranibizumab (Lucentis®) a VEGF inhibitor, for the treatment of DME. Initial results from this Phase 2 clinical study are anticipated in early Q3 2019. Results from this trial will provide the clinical data needed to plan the next stages of THR-317's clinical development.

Simultaneously inhibiting VEGF (ranibizumab) and PlGF (THR-317) could deliver better efficacy than either treatment alone. Non-clinical experiments indicate that anti-PlGF in the presence of an anti-VEGF antibody has an additive effect inhibiting the growth of new blood vessels (Van de Veire *et al.,*2010), a disease hallmark of DR.

Phase 2 clinical study evaluating THR-317 for treatment of MacTel1

In September 2018, Oxurion started a Phase 2 multi-center study evaluating the efficacy and safety of intravitreal THR-317 for the treatment of Macular Telangiectasia Type 1 (MacTel 1). MacTel 1 is a rare disease that affects the macula and can lead to vision loss. There is currently no effective treatment for MacTel 1.

This Phase 2 study plans to enroll 10 patients with macular edema caused by MacTel 1, who will each receive three 8mg intravitreal THR-317 injections over a period of 2 months. Efficacy and safety of the therapy will be assessed via functional and anatomic endpoints.

Initial results from this clinical study are anticipated towards the end of 2019.

THR-149 - a plasma kallikrein inhibitor for treatment of DME

Phase 1 study evaluating THR-149, a Potent Plasma Kallikrein inhibitor, for the treatment of DME

THR-149 is a novel plasma kallikrein inhibitor, generated by using Bicycle Therapeutics' Bicycles® technology platform, that is being developed for the treatment of DME.

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

Preclinical studies involving THR-149 were published in *The Journal of Medicinal Chemistry* in March 2018 and presented by Oxurion's senior scientist Dr Tine Van Bergen at the Annual Meeting of the European Association for the Study of Diabetes Eye Complications Study Group (EASDec). The data demonstrate the potency and efficacy of bicyclic peptide inhibitors of PKal, such as THR-149, via a VEGF-independent pathway.

In May 2018, Oxurion initiated a Phase 1 clinical study evaluating the safety of a single intravitreal injection of escalating dose levels of THR-149 in patients with DME. Oxurion announced in April 2019 that all patients had been enrolled in the clinical study, with initial results anticipated by early Q3.

THR-687 - an integrin antagonist for treatment of DME

Phase 1 study evaluating THR-687, a novel pan-RGD integrin antagonist for the treatment of DME

Oxurion is developing THR-687, a novel pan-RGD integrin antagonist, to preserve vision of a broad range of patients with diabetic eye disease. This wide-ranging potential is based on the hypothesis that integrin inhibition can address many of the processes that result in the pathological angiogenesis and vascular leakage that cause diabetic eye disease.

Oxurion is initially targeting THR-687 for DME. In September 2018, THR-687 initiated a Phase 1 multicenter, dose escalation study evaluating the safety of a single intravitreal injection of THR-687 for the treatment of patients with DME. A maximum of 15 patients will be enrolled, with initial results anticipated by the end of 2019.

Financial Update

Oxurion had €76.2 million in cash and investments at the end of March 2019. This compares with €85.1 million as of the end of December 2018.

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company currently developing a competitive pipeline of disease-modifying drug candidates for diabetic eye disease, a leading cause of blindness in people of working age worldwide.

Oxurion's most advanced drug candidate is THR-317, a PlGF inhibitor for the treatment of diabetic macular edema (DME), which is currently in a Phase 2 study in combination with Lucentis®. THR-317 is also being evaluated in a Phase 2 study for the treatment of Idiopathic Macular Telangiectasia Type 1 (MacTel 1), a rare retinal disease that affects the macula and can lead to vision loss.

Oxurion has two further pipeline candidates, THR-149, a plasma kallikrein inhibitor being developed for the treatment of DME; and THR-687, a pan-RGD integrin antagonist in development for the treatment of diabetic retinopathy and DME. Both THR-149 and THR-687 are in Phase 1 clinical studies.

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.
