- Topline data show that THR-149 is well-tolerated and safe. No dose-limiting toxicities or drug-related serious adverse events reported.
- Rapid onset of action starting at Day 1 with increasing average improvement in Best Corrected Visual Acuity (BCVA) of up to 7.5 letters at Day 14 following a single injection of THR-149.
- Activity maintained with an average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149.

Leuven, Belgium , 1 July 2019 – 07.30 AM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing innovative treatments to preserve vision in patients with diabetic eye disease, today reports positive topline data from a Phase 1 study with THR-149, a novel, potent, plasma kallikrein (PKal) inhibitor for the treatment of Diabetic Macular Edema (DME). THR-149 has been developed in partnership with Bicycle Therapeutics (Nasdaq: BCYC). Oxurion holds the exclusive license to the PKal inhibitor portfolio originating from this partnership.

The Phase 1 open-label, multicenter (US), non-randomized trial evaluated the safety of a single intravitreal (IVT) injection of THR-149, a novel PKal inhibitor, at 3 ascending dose levels in 12 subjects with visual impairment due to center-involved DME (CI-DME) *(NCT03511898)*.

Topline data from the trial show that THR-149 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.

The study also looked at efficacy including changes to the patient's Best Corrected Visual Acuity (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. This activity was maintained with an average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149.

Oxurion is currently preparing the complete data analysis from this Phase 1 study with THR-149 and plans to present further clinical data at Euretina in Paris and AAO in San Francisco later this year.

Encouraging preclinical data showing the potency and efficacy of bicyclic peptide inhibitors of PKal, such as THR-149 were published in *The Journal of Medicinal Chemistry* in March 2018.

Activation of the PKal, a VEGF independent pathway, has been shown to induce several of the disease hallmarks of DME including retinal vascular permeability, microaneurysm and inflammation. Elevated levels of plasma kallikrein has been reported in patients with DME.[1]
Pravin Dugel, M.D., Managing Partner of Retinal Consultants of Arizona and Clinical Professor of Roski Eye Institute, Keck USC School of Medicine, commented on the study results, "*The topline data from this Phase 1 study show that THR-149 is safe and well tolerated at all of the dose levels tested. I am very encouraged to see the signs of efficacy so early on post treatment, and to see a clear durable benefit to the patient's vision as measured by BCVA."*

Dr Dugel added: "The PKal pathway is a VEGF independent pathway and these results give me confidence that PKal inhibitors, such as THR-149, hold the potential to provide an important additional new treatment option for patients with DME."

Patrik De Haes, M.D., CEO of Oxurion, said: "*We are delighted by these encouraging topline data, which confirm that THR-149 is not only well-tolerated and safe for intravitreal use, but also provides a rapid and sustained gain in BCVA. These positive findings provide us with the information and confidence needed to plan the next stage of THR-149's clinical development.*

They also demonstrate that THR-149 has the potential to become the best-in-class PKal inhibitor for the treatment of DME."

END

For further information please contact:

Oxurion NV	
Wouter Piepers, Global Head of Investor Relations & Corporate Communications +32 16 75 13 10 / +32 478 33 56 32 wouter.piepers@oxurion.com	
EU - Citigate Dewe Rogerson David Dible/ Sylvie Berrebi Tel: +44 20 7638 9571 oxurion@citigatedewerogerson.com	US - LifeSci Public Relations Alison Chen +1 646-876-4932 achen@lifescipublicrelations.com