



## **Bicycle Therapeutics Announces First Patient Dosed in Oxurion's Phase II Trial Using a Novel Bicycle®-based Plasma Kallikrein Inhibitor for the Treatment of Diabetic Macular Edema**

September 1, 2020

CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--Sep. 1, 2020-- [Bicycle Therapeutics plc](#) (NASDAQ: BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycle*®) technology, today announced that the first patient has been dosed in Oxurion's Phase II study of THR-149, a novel *Bicycle*-based plasma kallikrein (PKal) inhibitor, in patients with diabetic macular edema (DME).

"*Bicycles* are a new modality with unique properties that provide a differentiated approach for the treatment of a wide range of diseases, which we are exploring through our strategic partnerships with therapeutic specialists such as Oxurion," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. "In addition to positive safety and tolerability results, during the Phase I trial of THR-149, investigators observed that patients experienced a sustained improvement in best corrected visual acuity for 90 days following a single administration of THR-149. In the Phase II study, we hope to learn more about the potential utility of *Bicycles* in treating DME, an ophthalmic condition for which there is an urgent need for additional medicines."

"An estimated 40% of patients with DME do not respond optimally to anti-VEGF monotherapy, which is the standard of care," said Patrik De Haes, M.D., Chief Executive Officer of Oxurion. "Given the high unmet need in this patient population and the positive Phase I safety and tolerability data, we believe THR-149 could provide an important new mechanism of action for treating patients with this debilitating disease. We look forward to building on the Phase I results as we advance THR-149 into this next stage of clinical development."

The Phase II trial, named KALAHARI, is expected to include approximately 122 patients with central involved DME who do not respond adequately to anti-VEGF and will be comprised of two parts. Part A (n=18) is a dose-ranging study in which three dose levels, including multiple administrations of THR-149, will be evaluated. The primary objective of Part A is to identify the optimal dose to be used in Part B of the trial. Part B (n≈104) is a double-blind active control study that will evaluate the efficacy of THR-149 at the dose level selected in Part A versus the comparator aflibercept.

### **About Bicycle Therapeutics**

Bicycle Therapeutics (NASDAQ: BCYC) is a clinical-stage biopharmaceutical company developing a novel class of medicines, referred to as *Bicycles*®, for diseases that are underserved by existing therapeutics. *Bicycles* are fully synthetic short peptides constrained with small molecule scaffolds to form two loops that stabilize their structural geometry. This constraint facilitates target binding with high affinity and selectivity, making *Bicycles* attractive candidates for drug development. Bicycle's lead product candidate, BT1718, a *Bicycle* Toxin Conjugate (BTC) that targets MT1-MMP, is being investigated in an ongoing Phase I/IIa clinical trial in collaboration with the Centre for Drug Development of Cancer Research UK. Bicycle is also evaluating BT5528, a second-generation BTC targeting EphA2, in a Company-sponsored Phase I/II trial. Bicycle is headquartered in Cambridge, UK with many key functions and members of its leadership team located in Lexington, MA. For more information, visit [bicycletherapeutics.com](http://bicycletherapeutics.com).

### **About Oxurion**

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard 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 developing two novel therapeutics for the treatment of DME, one of which is THR-149, a plasma kallikrein inhibitor being developed in conjunction with Bicycle Therapeutics plc as a potential new standard of care for DME patients who respond sub-optimally to anti-VEGF therapy.

Oxurion is headquartered in Leuven, Belgium.

### **Forward Looking Statements**

This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements the clinical development of THR-149 or any of Bicycle's other product candidates or programs, the progression and design of Oxurion's Phase II clinical trial of THR-149, Bicycle's ongoing collaboration with Oxurion, and the therapeutic potential for THR-149 or other *Bicycles* in the treatment of diabetic macular edema. Bicycle may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: uncertainties inherent in the initiation and completion clinical trials and clinical development of Bicycle's product candidates; availability and timing of results from clinical trials; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle's product candidates; risks related to Bicycle's ability to maintain existing collaborations and realize the benefits thereof; expectations for regulatory approvals to conduct trials or to market products; risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to Bicycle's and its

collaboration partners' abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, are described in greater detail in the section entitled "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 5, 2020, as well as in other filings Bicycle may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Bicycle expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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