

# Bicycle

## Bicycle Therapeutics Announces First Patient Dosed in Phase I/II Trial of Bicycle® Tumor-targeted Immune Cell Agonist™ BT7480 in Patients with Advanced Solid Tumors Associated with Nectin-4 Expression

November 4, 2021

- BT7480 is the Company's Fourth Product Candidate to Enter the Clinic in the Past Four Years

- This is Bicycle's First Immuno-oncology Asset to Enter the Clinic

CAMBRIDGE, England, & BOSTON--(BUSINESS WIRE)--Nov. 4, 2021-- 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 the Phase I dose escalation portion of a company-sponsored Phase I/II trial of BT7480, a novel, fully synthetic *Bicycle* tumor-targeted immune cell agonist™ (*Bicycle* TICA™) targeting Nectin-4 and agonizing CD137. Preclinical studies have demonstrated that BT7480 activates CD137 only in the presence of Nectin-4 expressing tumor cells. The Phase I/II trial of BT7480 will be conducted in patients with advanced solid tumors associated with Nectin-4 expression.

"BT7480 is our first *Bicycle* TICA to enter the clinic and is one of a new class of tumor-targeting agents," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. "Overexpression of Nectin-4, a well-validated tumor antigen, has been observed in several common tumor types and is associated with poor disease prognosis. Activation of CD137, a co-stimulatory receptor expressed on multiple components of the immune system, can drive anti-tumor immunity, but activation outside of the tumor may give rise to toxicity. Preclinical studies have shown encouraging results, and we look forward to studying the safety and efficacy of this unique asset as we begin the dose escalation portion of the trial."

The Phase I/II multi-center, open-label trial will evaluate BT7480 administered once weekly. Enrollment is ongoing in the Phase I dose escalation of BT7480 given as a monotherapy, and the Company plans to evaluate BT7480 dosed in combination with nivolumab in future Phase I dose escalation cohorts. The Phase I portion of the trial is primarily designed to assess the safety and tolerability of BT7480, and to determine a recommended Phase II dose (RP2D). Following selection of an RP2D, Bicycle expects to initiate a Phase II dose expansion portion with the primary objective of evaluating the clinical activity of BT7480 as monotherapy and in combination with nivolumab in patients with Nectin-4-positive tumors.

### 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 is evaluating BT5528, a second-generation *Bicycle* Toxin Conjugate (BTC™) targeting EphA2; BT8009, a second-generation BTC targeting Nectin-4, a well-validated tumor antigen; and BT7480, a *Bicycle* TICA™ targeting Nectin-4 and agonizing CD137, in company-sponsored Phase I/II trials. In addition, BT1718, a BTC that targets MT1-MMP, is being investigated in an ongoing Phase I/IIa clinical trial sponsored by the Cancer Research UK Centre for Drug Development. 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](https://www.bicycletherapeutics.com).

### 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 regarding the clinical development of BT7480 or any of Bicycle's other product candidates or programs; the expected design of Bicycle's clinical trial of BT7480; the anticipated progression of clinical trials; the safety, tolerability or efficacy of BT7480; and the potential benefits of BT7480 or any of Bicycle's other product candidates. 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: risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to Bicycle's abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; uncertainties inherent in the initiation and completion of 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; expectations for regulatory approvals to conduct trials or to market product; and other important factors, any of which could cause Bicycle's actual results to differ from those contained in the forward-looking statements, are described in greater detail in the section entitled "Risk Factors" in Bicycle's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 5, 2021, 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 because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

**Investors:**

David Borah, CFA

VP, Capital Markets & Investor Relations

[david.borah@bicycletx.com](mailto:david.borah@bicycletx.com)

617-203-8300

**Media:**

Consilium Strategic Communications

Sukaina Virji or Mary-Jane Elliott

[bicycle@consilium-comms.com](mailto:bicycle@consilium-comms.com)

Source: Bicycle Therapeutics plc