Bicycle Therapeutics Announces FDA Fast Track Designation Granted to BT8009 for the Treatment of Adult Patients with Previously Treated Locally Advanced or Metastatic Urothelial Cancer

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CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--Jan. 4, 2023-- 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 United States Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to Bicycle's BT8009 monotherapy for the treatment of adult patients with previously treated locally advanced or metastatic urothelial cancer. BT8009 is a potential first in class Bicycle Toxin Conjugate (BTC®) targeting Nectin-4, a protein that is highly expressed in urothelial cancer (UC) and other solid tumors.

"FTD represents another positive step in the development of BT8009 and reflects the pressing need for a clinically meaningful, differentiated therapy compared to what is available for patients," said Kevin Lee, Ph.D., Chief Executive Officer. "We believe this designation is a valuable component of our future clinical and regulatory strategy as we work to align with the FDA to address the pressing unmet needs of people living with urothelial cancer."

FTD is intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition. This unmet medical need is defined as providing a therapy where either none exists or providing a therapy which may prove superior to existing therapy. A clinical program that receives FTD may benefit from more frequent meetings and communications with the FDA to discuss development plans and ensure the collection of appropriate data needed to support approval. Clinical programs conducted under FTD may be eligible for Accelerated Approval and Priority Review if relevant criteria are met. More information on the Fast Track process is available here.

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.

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 potential of BT8009 to target and kill cancer tumor cells; the initiation, progress, and timing of clinical trials of BT8009; and whether Bicycle will experience delay in or failure to obtain regulatory approval of Bicycle's product candidates and successful compliance with FDA and other governmental regulations applicable to product approvals. Bicycle may not actually achieve the 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 intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: whether the outcomes of preclinical studies will be predictive of clinical trial results; the risk that trials and studies may be delayed and may not have satisfactory outcomes; 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 November 3, 2022, 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.

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