

Bicycle

Bicycle Therapeutics and Cancer Research UK to Collaborate on Development of New Bicycle® Immuno-oncology Candidate, BT7401

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Cancer Research UK to fund exploratory development of BT7401 through a Phase IIa clinical study

LONDON & CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--Jan. 7, 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 a second collaboration with Cancer Research UK, the world's largest independent funder of cancer research, in which Cancer Research UK will fund and sponsor development of BT7401, a multivalent *Bicycle* CD137 agonist, through a Phase IIa clinical study.

"The modular nature of the Bicycle platform enables a number of opportunities to generate new therapeutics that could address unmet need in oncology and other serious diseases," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle. "This new collaboration marks yet another initiative designed to help us bring a potentially important *Bicycle*-based therapy to patients more efficiently. We are excited to extend our relationship with Cancer Research UK by collaborating with them on BT7401. Cancer Research UK is a partner of choice, with a broad network of collaborators and extensive expertise in cancer treatment. Through our collaboration, we believe we will be able to characterize the biologic and therapeutic profile of BT7401, which we're pleased to add to our growing portfolio of novel immuno-oncology assets."

Dr. Nigel Blackburn, Cancer Research UK's director of drug development, said: "We're delighted to be partnering again with Bicycle, building on our continuing relationship. Based on the preclinical data, we believe that BT7401 could offer improved anti-tumor activity with fewer side effects compared with antibody-based approaches, which so far have been limited by toxicity."

Dr. Blackburn continued: "Looking to the future, we believe BT7401 has the potential to open up new treatment options for the large numbers of patients who stop responding to checkpoint inhibitors, and we look forward to working with Bicycle in this new endeavor."

BT7401 is a chemically synthesized, multivalent small molecule agonist of CD137, comprised of *Bicycles* connected by stable linkers through a central hinge. Though prior programs using antibodies to agonize CD137 have demonstrated robust and durable anti-tumor effects, they have been limited by severe hepatotoxicity observed in clinical trials. Preliminary toxicology studies suggest BT7401 may circumvent this limitation. In addition, BT7401 has shown significant pharmacologic activity in preclinical models. These findings indicate that BT7401 may offer an improved therapeutic index compared to that of antibody-based approaches.

Under the terms of the Clinical Development Partnerships agreement, Cancer Research UK's Centre for Drug Development will fund and sponsor development of BT7401 from current preclinical studies through the completion of a Phase IIa trial. Bicycle retains the right to advance the BT7401 program further, at which point an undisclosed payment split between cash and equity, success-based milestones and royalty payments would be made to Cancer Research UK.

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 study. 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.

About Cancer Research UK's Centre for Drug Development

Cancer Research UK has an impressive record of developing novel treatments for cancer. The Cancer Research UK Centre for Drug Development has been pioneering the development of new cancer treatments for 25 years, taking over 140 potential new anti-cancer agents into clinical trials in patients. It currently has a portfolio of 21 new anti-cancer agents in preclinical development, Phase I or early Phase II clinical trials. Six of these new agents have made it to market including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase III trials.

About Cancer Research UK's Commercial Partnerships Team

Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research. Cancer Research UK's specialist Commercial Partnerships Team works closely with leading international cancer scientists and their institutes to protect intellectual property arising from their research and to establish links with commercial partners. Cancer Research UK's commercial activity operates through Cancer Research Technology Ltd., a wholly owned subsidiary of Cancer Research UK. It is the legal entity which pursues drug discovery research in themed alliance partnerships and delivers varied commercial partnering arrangements.

About Cancer Research UK

- Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research.
- Cancer Research UK's pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives.
- Cancer Research UK receives no funding from the UK government for its life-saving research. Every step it makes towards beating cancer relies on vital donations from the public.
- Cancer Research UK has been at the heart of the progress that has already seen survival in the UK double in the last 40 years.
- Today, 2 in 4 people survive their cancer for at least 10 years. Cancer Research UK's ambition is to accelerate progress so that by 2034, 3 in 4 people will survive their cancer for at least 10 years.
- Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.
- Together with its partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured.

For further information about Cancer Research UK visit www.cancerresearchuk.org.

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 our collaboration with Cancer Research UK; the discovery of potential product candidates using our technology; the anticipated clinical advancement of BT7401; the possible results of clinical trials; the therapeutic potential of BT7401; and the development of potential 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: the risk that we may not realize the intended benefits of our technology, including that we may not identify and develop additional product candidates; the risk that we may not be able to maintain existing collaborations and realize the benefits thereof or develop new relationships; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Bicycle's product candidates; availability and timing of results from preclinical studies and clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial; 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 BT7401 or other product candidates; expectations for regulatory approvals to conduct trials or to market product; and other important factors 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 November 7, 2019, 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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