



## **Bicycle Therapeutics to Present New Translational Data for BT1718 and Preclinical Data for Other Bicycle® Toxin Conjugates at AACR-NCI-EORTC 2019**

October 16, 2019

CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--Oct. 16, 2019-- [Bicycle Therapeutics plc](#) (NASDAQ: BCYC) a clinical-stage biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycles*®) product platform, today announced that new translational data for BT1718 and preclinical data for BT5528 and BT8009 will be presented during poster sessions at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on October 26-30, 2019 in Boston, MA.

New translational data will be presented for BT1718, the Company's lead *Bicycle*® Toxin Conjugate (BTC) product candidate, which define enrollment criteria for identifying expansion cohorts in the Phase IIa part of the ongoing Phase I/IIa trial with BT1718. The Phase I/IIa study, sponsored by Cancer Research UK, is currently in Phase I dose escalation in patients with advanced solid tumors who have not been pre-selected for MT1-MMP status. Once a recommended once-weekly Phase II dose is established, the Company expects to initiate the Phase IIa expansion, which will include patients determined to be MT1-MMP-positive based on a prespecified tumor membrane H-score. Initially, patients will be enrolled into two expansion cohorts, one in squamous lung cancer and the other in an all-comers "basket" cohort. Depending on results from these first two cohorts, additional cohorts may be initiated.

"We are creating a pipeline of *Bicycle* Toxin Conjugates, which selectively deliver toxin payload to tumors in a manner we believe is unique and differentiated to that of antibody drug conjugates," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. "We intend to maximize chances of success in the clinic for these innovative medicines by applying well-validated translational approaches to inform tumor type selection and patient enrollment criteria. As the data to be presented supports, we believe we have developed a compelling rationale for the design of the Phase IIa part of the ongoing trial and look forward to advancing BT1718 into the expansion cohorts, following dose selection."

Additional preclinical data will also be presented for Bicycle's other BTC programs, BT5528 and BT8009, which show target-dependent anti-tumor activity across a range of EphA2-expressing and Nectin-4-expressing cancer models, respectively.

Details on Bicycle's presentations at AACR-NCI-EORTC are as follows:

Session Title: Poster Session A

Location: Level 2, Hall D

Poster Presentation Title: MT1-MMP Immunohistochemistry (IHC) analysis of tumor microarrays (TMAs) using a novel scoring system guides patient selection for BT1718 expansion cohorts

Abstract #: A047

Date & Time: October 27, 2019, 12:30 p.m. – 4:00 p.m. ET

Session Title: Poster Session C

Location: Level 2, Hall D

Poster Presentation Title: BT5528, a Bicycle Toxin Conjugate targeting EphA2: mechanism of action and clinical translation

Abstract #: C066

Date & Time: October 29, 2019, 12:30 p.m. – 4:00 p.m. ET

Session Title: Poster Session C

Location: Level 2, Hall D

Poster Presentation Title: BT8009, a Bicycle Toxin Conjugate targeting Nectin-4, shows target selectivity, and efficacy in preclinical large and small tumor models

Abstract #: C061

Date & Time: October 29, 2019, 12:30 p.m. – 4:00 p.m. ET

The posters will be available on the Publications section of [bicycletherapeutics.com](#) following the presentation.

### **About BT1718**

BT1718 is a *Bicycle*® Toxin Conjugate being developed by Bicycle Therapeutics that targets Membrane Type 1 Matrix Metalloproteinase (MT1-MMP), also known as MMP-14, which has an established role in cell invasion and metastasis, is linked to poor outcomes and is over-expressed in many solid tumors. BT1718 has demonstrated promising target-dependent efficacy in preclinical models, including both cell- and patient-derived xenografts that are resistant to treatment with standards of care. In addition, it shows only a subset of the toxicities typically associated with other highly potent cancer treatments.

### **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, is a *Bicycle*® Toxin Conjugate being investigated in an

ongoing Phase I/IIa clinical trial in collaboration with the Centre for Drug Development of Cancer Research UK. 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 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, formerly the Drug Development Office, 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 around 30 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. This rate of success is comparable to that of any pharmaceutical company.

#### **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's work or to find out how to support the charity, please call 0300 123 1022 or visit [www.cancerresearchuk.org](http://www.cancerresearchuk.org). Follow us on Twitter and Facebook.*

#### **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 BT1718 or any of Bicycle's other product candidates or programs, the progression of Bicycle's ongoing Phase I/IIa clinical trial of BT1718 into Phase IIa, the expected cohort composition of the Phase IIa expansion of this clinical trial, and the anticipated dose selection in this clinical trial. 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 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 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 BT1718 or other 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 product; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, as described in greater detail in the section entitled "Risk Factors" in the final prospectus for our initial public offering, filed with the Securities and Exchange Commission (SEC) on May 23, 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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