Bayer and Bicycle Therapeutics Enter Strategic Collaboration for Development of Novel Targeted Radionuclide Therapies in Oncology

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- Collaboration will leverage Bicycle Therapeutic's synthetic peptides for the discovery and development of multiple targeted radioconjugates of the company in oncology
- Advancing the use of bicycle peptides as a novel targeting approach in radiopharmaceuticals
- Bicycle Therapeutics to receive upfront payment of USD 45 million, and potential future development and commercial-based milestones, up to a total of USD 1.7 billion, plus tiered commercial royalties

BERLIN & CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--May 10, 2023-- Bayer and Bicycle Therapeutics plc (NASDAQ: BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics by utilizing proprietary bicyclic peptides technology (Bicycle®), today announced that they have entered into a strategic collaboration agreement to discover, develop, manufacture, and commercialize Bicycle radioconjugates for multiple agreed upon oncology targets.

Bicyclic peptides are peptides consisting of 9-20 amino acids that can be synthetically manufactured and bind to targets with high affinity and selectivity, affording high tumor penetration and fast excretion from healthy organs. They are chemically synthesizable, featuring a low molecular weight and tunable pharmacokinetics, with a large surface-area for molecular interactions that allows protein-protein interactions to be targeted. The two companies will jointly use Bicycle's peptide technology to develop bicyclic peptides for several undisclosed oncology targets. Targeted radiotherapies are an innovative class of cancer therapies. Due to their unique mode of action, they have the potential to unlock a broad opportunity space and serve patients in high-unmet medical need indications.

"At Bayer, we enter strategic collaborations to expand our access to innovation," said Christian Rommel, Ph.D., Global Head of Research and Development and Member of the Executive Committee, Pharmaceuticals Division, Bayer. "With Bicycle's proprietary peptide-based technology, we continue to strengthen our oncology development pipeline by adding next-generation targeted radiotherapeutics to address high unmet medical needs of cancer patients."

"Bayer is a pioneer in the radiopharmaceuticals space and provides new and additional validation of our unique technology," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. "We believe our bicyclic peptide platform, coupled with Bayer's scale and expertise in developing radiopharmaceuticals, has the potential to deliver improved clinical outcomes for patients with cancer. We look forward to collaborating with Bayer to bring forth new potential first-in-class radiopharmaceutical treatments based on Bicycles."

Under the terms of the agreement, Bayer and Bicycle will collaborate on the development of bicyclic peptides for multiple oncology targets. Bicycle will utilize its proprietary phage platform to discover and develop bicyclic peptides and Bayer will be responsible for, and fully fund, all further preclinical and clinical development, manufacturing, and commercialization activities. Bicycle will receive a $45 million upfront payment and with potential development and commercial-based milestone fees, payments to Bicycle could total up to $1.7 billion. Bicycle will also be eligible to receive mid-single to double-digit tiered royalties on Bicycle-based medicines commercialized by Bayer. The closing of the transaction is subject to clearance of the transaction under the U.K. National Security and Investment Act 2021.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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 Cambridge, MA. For more information, visit bicycletherapeutics.com.

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the

Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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 Bicycle’s collaboration with Bayer; the discovery, development, manufacture and potential commercialization of potential product candidates using Bicycle’s technology and under the strategic collaboration agreement; the therapeutic potential for Bicycles in oncology and other applications; and the potential to receive milestone payments and royalties under the strategic collaboration agreement. 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 Bicycle may not realize the intended benefits of its technology or of the collaboration agreement with Bayer, including that Bicycle and Bayer may not successfully identify, develop, manufacture and commercialize any product candidates; and other important factors, any of which could cause Bicycle’s actual results to differ from those contained in the forward-looking statements and which are described in greater detail in the section entitled “Risk Factors” in Bicycle’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2023, 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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