Cardiff Oncology Enters Agreement with PoC Capital to Fund Phase 2 Clinical Trial of Onvansertib in KRAS-Mutated Metastatic Colorectal Cancer (mCRC)

- Funding will also enable the addition of new trial sites to accelerate completion of the Phase 2 clinical trial
- Data continues to demonstrate the safety and efficacy of onvansertib as a promising new treatment for patients with KRAS-mutated mCRC

SAN DIEGO, May 13, 2020 /PRNewswire/ -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage oncology therapeutics company developing drugs to treat cancers with the greatest medical need for new treatment options, including KRAS-mutated colorectal cancer, Zytiga®-resistant prostate cancer and leukemia, today announced an agreement with PoC Capital, LLC, to fund the completion of its ongoing Phase 1b/2 clinical trial in patients with KRAS-mutated metastatic Colorectal Cancer (mCRC).

"We are pleased to be able to support the second phase of Cardiff Oncology's clinical study of onvansertib in patients with KRAS-mutated colorectal cancer," said Daron Evans, Managing Director of PoC Capital. "The response in patients enrolled in the first phase of this study is very encouraging and we are optimistic that patients will soon have a new therapeutic option to treat their cancer."

Cardiff Oncology's agreement with PoC Capital follows the Company's announcement of positive safety and efficacy data from its Phase 1b trial, presented at the American Association for Cancer Research (AACR) conference. The data demonstrate clinical benefit in patients treated with onvansertib in combination with second line standard-of-care, FOLFIRI/Avastin. Seven out of eight (88%) evaluable patients achieved a clinical response (partial response + stable disease) and progression-free survival (PFS) of 6.5 months, which exceeds the current standard-of-care response rate of 4% and median PFS of 5.5 months. Additional trial data will be presented as a virtual oral poster presentation at the American Society of Clinical Oncology (ASCO) annual meeting on Friday, May 29, 2020.

"Our agreement with PoC Capital is an important milestone and recognition of the efficacy we are already observing in our ongoing clinical trial targeting KRAS-mutated mCRC, an indication of high unmet medical need," said Dr. Mark Erlander, Chief Executive Officer of Cardiff Oncology. "We are pleased to continue our partnership with PoC Capital and advance our clinical development of onvansertib and address the once considered 'undruggable' KRAS mutation in an effort to improve response to treatment in patients who have previously been faced with a very poor prognosis."

Colorectal cancer (CRC) is the second leading cause of cancer death in the U.S. Despite significant progress in the treatment of mCRC, the majority of patients with metastatic disease succumb to the disease. Therefore, improving the treatment options and effectiveness is critical in changing the outcomes for this patient population. The efficacy of second-line therapy in terms of survival prolongation and response remains very limited, particularly in the KRAS-mutated population, where treatment options are more restricted. The response rate in the second-line setting is 4% and the median progression-free survival is 5.5 months as reported in a large international trial.

About the Phase 1b/2 Clinical Trial of Onvansertib in mCRC

In this open-label, Phase 1b/2 trial, onvansertib in combination with standard-of-care FOLFIRI and Avastin® is being evaluated for safety and efficacy in patients with KRAS-mutated mCRC. The trial, A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for
Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation, will enroll up to 44 patients with a KRAS mutation and histologically confirmed metastatic and unresectable disease. In addition, patients must have failed treatment or be intolerant of FOLFOX (fluoropyrimidine and oxaliplatin) with or without Avastin® (bevacizumab). The trial is being conducted at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and The Mayo Clinic Arizona.

About Onvansertib

Onvansertib is a first-in-class, third-generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK1) enzyme, which is over-expressed in multiple cancers including leukemias, lymphomas and solid tumors. Onvansertib targets the PLK1 isoform only (not PLK2 or PLK3), is orally administered and has a 24-hour half-life with only mild-to-moderate side effects reported. Cardiff Oncology believes that targeting only PLK1 and having a favorable safety and tolerability profile, along with an improved dose/scheduling regimen will significantly improve on the outcome observed in previous studies with a former panPLK inhibitor in AML.

Onvansertib has demonstrated synergy in preclinical studies with numerous chemotherapies and targeted therapeutics used to treat leukemias, lymphomas and solid tumor cancers, including irinotecan, FLT3 and HDAC inhibitors, taxanes and cytotoxins. Cardiff Oncology believes the combination of onvansertib with other compounds has the potential to improve clinical efficacy in acute myeloid leukemia (AML), metastatic castration-resistant prostate cancer (mCRPC), non-Hodgkin lymphoma (NHL), colorectal cancer and triple-negative breast cancer (TNBC), as well as other types of cancer.

Cardiff Oncology has three ongoing clinical trials of onvansertib: A Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with mCRPC who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving Zytiga® (NCT03414034); a Phase 1b/2 Study of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation (NCT03829410; and a Phase 2 clinical trial of onvansertib in combination with decitabine in patients with relapsed or refractory AML (NCT03303339).

Cardiff Oncology licensed onvansertib (also known as NMS-1286937 and PCM-075) from Nerviano Medical Sciences (NMS), the largest oncology-focused research and development company in Italy, and a leader in protein kinase drug development. NMS has an excellent track record of licensing innovative drugs to pharma/biotech companies, including Array (recently acquired by Pfizer), Ignyta (acquired by Roche) and Genentech.

About Cardiff Oncology, Inc.

Cardiff Oncology (formerly Trovagene, Inc.) is a clinical-stage biotechnology company with the singular mission of developing new treatment options for cancer patients in indications with the greatest medical need. Our goal is to overcome resistance, improve response to treatment and increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 (PLK1) inhibitor, in combination with standard-of-care chemotherapy and targeted therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to enable assessment of patient response to treatment. We have three ongoing clinical programs that are demonstrating the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in Zytiga-resistant metastatic castration-resistant prostate cancer (mCRPC); and a Phase 2 study of onvansertib in combination with decitabine in relapsed or refractory acute myeloid leukemia (AML). For more information, please visit https://cardiffoncology.com/.
Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Cardiff Oncology's expectations, strategy, plans or intentions. These forward-looking statements are based on Cardiff Oncology's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our need for additional financing; our ability to continue as a going concern; clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove to be commercially successful. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any precision medicine therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Cardiff Oncology's Form 10-K for the year ended December 31, 2019, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Cardiff Oncology does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Cardiff Oncology Contact:
Vicki Kelemen
VP, Clinical Development and Investor Relations
858-952-7652
vkelemen@cardiffoncology.com

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