Cardiff Oncology Announces Publication of Data from Phase 1b study in second-line KRAS-mutated mCRC in Clinical Cancer Research

January 17, 2024

- Findings from the Phase 1b portion of company's Phase 1b/2 study in second-line KRAS-mutated mCRC highlight the safety and promising efficacy of onvansertib in combination with standard-of-care -

- These peer-reviewed published data are part of the Phase 1b/2 data Cardiff Oncology announced in August 2023 and informed the shift to investigation in first-line in RAS-mutated mCRC (CRDF-004)-

SAN DIEGO, Jan. 17, 2024 /PRNewswire/ -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced that the findings of the Phase 1b portion of the Phase 1b/2 study for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC) disclosed by Cardiff Oncology in August 2023 have been published in the peer-reviewed journal *Clinical Cancer Research*, a journal of the American Association for Cancer Research.

The publication underscores the safety profile of onvansertib when combined with the standard-of-care (SoC) chemotherapy+bevacizumab. The results show that the combination has a lasting response, indicating its tolerability and efficacy in treating mCRC patients whose tumors harbor various KRAS mutations.

Onvansertib is a highly specific Polo-like kinase 1 (PLK1) inhibitor that has shown tolerability as a single agent and in combination with multiple chemotherapies in various solid tumors. Additional data from the full Phase 1b/2 study for the second-line treatment of patients with KRAS-mutated mCRC will be presented at the upcoming American Association for Cancer Research (AACR) Annual Meeting in April 2024. These compelling insights, along with the agreement from the US FDA, led to Cardiff Oncology's decision to initiate a first-line trial (CRDF-004) in RAS-mutated mCRC.

"Our groundbreaking Phase 1b study targeted the KRAS-mutated mCRC patient population that has limited effective treatment options, and for whom there has been no new targeted therapy approved in decades. The Phase 1b study revealed the safety and enhanced efficacy of integrating onvansertib, an oral PLK1 inhibitor, with SoC FOLFIRI+bevacizumab in KRAS-mutated second-line mCRC patients," said Dr. Fairooz Kabbinavar MD, FACP, Chief Medical Officer of Cardiff Oncology and one of the article's lead authors. "Our study showed an improved objective response rate and median progression-free survival compared to historical controls. Encouragingly, the FOLFIRI+bevacizumab+onvansertib combination demonstrated efficacy across multiple KRAS mutations. Our upcoming presentation at AACR will showcase the full Phase 1b/2 data from all 68 patients in the study. The data from this Phase 1b/2 study serves as the foundation for our CRDF-004 first-line study in RAS-mutated mCRC, which is now open for enrollment at multiple centers."

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers. The Company's lead asset is onvansertib, a PLK1 inhibitor being evaluated in combination with standard-of-care (SoC) therapeutics in clinical programs targeting indications such as RAS-mutated metastatic colorectal cancer (mCRC) and metastatic pancreatic ductal adenocarcinoma (mPDAC), as well as in investigator-initiated trials in small cell lung cancer (SCLC) and triple negative breast cancer (TNBC). These programs and the Company's broader development strategy are designed to target tumor vulnerabilities in order to overcome treatment resistance and deliver superior clinical benefit compared to the SoC alone. For more information, please visit https://www.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 using 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 several 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, 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 candidate; 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; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that our product candidate 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, 2022, 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.

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