Cardiff Oncology Announces Completion of Enrollment in Phase 2 CRDF-004 Trial Evaluating Onvansertib for the Treatment of First-line RAS-mutated Metastatic Colorectal Cancer

April 15, 2025

- Initial results from randomized Phase 2 CRDF-004 trial in RAS-mut mCRC were released in December 2024 -

- Additional clinical data from CRDF-004 trial expected in 1H 2025 -

SAN DIEGO, April 15, 2025 (GLOBE NEWSWIRE) -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced completion of patient enrollment in the ongoing Phase 2 CRDF-004 trial evaluating onvansertib in combination with standard of care (SoC) for the treatment of first-line RAS-mutated metastatic colorectal cancer (mCRC).

“The successful completion of enrollment in our first-line trial for patients with RAS mutant mCRC represents an important milestone in our mission to develop new treatments for a population who have not seen meaningful treatment advancements for decades. We are deeply grateful for our patients, care-givers and clinical investigators, whose commitment to the trial has been integral in this achievement,” said Mark Erlander, Chief Executive Officer of Cardiff Oncology. “As we move forward, we are eager to continue accruing additional clinical data and advancing towards regulatory discussions with FDA with the goal of bringing this transformative therapy to patients.”

The Phase 2 CRDF-004 trial has reached our targeted enrollment of patients with first-line mCRC across 41 clinical sites in the U.S. Patients in the trial have a documented KRAS or NRAS mutation with unresectable disease. Onvansertib is added to SoC consisting of FOLFIRI plus bevacizumab or FOLFOX plus bevacizumab. Patients are randomized to either 20mg of onvansertib plus SoC, 30mg of onvansertib plus SoC, or SoC alone. The primary endpoint is objective response rate (ORR), and the secondary endpoints include progression-free survival (PFS), duration of response (DOR) and safety.

The company anticipates reporting additional clinical data from the CRDF-004 trial in the first half of 2025.

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), as well as in ongoing and planned investigator-initiated trials in metastatic pancreatic ductal adenocarcinoma (mPDAC), 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; results of preclinical studies or clinical trials for our product candidate could be unfavorable or delayed; our need for additional financing; risks related to business interruptions, including the outbreak of COVID-19 coronavirus and cyber-attacks on our information technology infrastructure, 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 our product candidate 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, 2024, 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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