Cardiff Oncology Announces Journal of Clinical Oncology Publication of Data from Phase 2 Trial in Second-line KRAS Mutant mCRC

October 30, 2024

- Findings underscore that the combination of onvansertib with FOLFIRI and bevacizumab demonstrates clinical activity and is well tolerated in second-line KRAS-mutant mCRC -

- Post hoc analysis resulted in a 7.7-fold higher clinical benefit in bev-naïve patients with an ORR of 77% compared to 10% in bev-exposed patients -

- Results from this trial, along with translational studies, supported the transition of clinical development of onvansertib to first-line RAS-mutant mCRC -

- Initial readout from first-line RAS-mutant mCRC CRDF-004 trial expected in H2 2024 -

SAN DIEGO, Oct. 30, 2024 (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 the publication of data from our Phase 2 trial evaluating onvansertib in combination with FOLFIRI and bevacizumab (bev) for the second-line treatment of KRAS mutant metastatic colorectal cancer (mCRC) in the peer-reviewed *Journal of Clinical Oncology*, the flagship publication of the American Society of Clinical Oncology (ASCO).

“It is exciting to see novel therapies in development that are well tolerated and demonstrate clinical activity in KRAS mutant mCRC, a cancer indication that has lacked new treatment options for decades,” said Heinz-Josef Lenz, MD, Professor of Medicine, J. Terrence Lanni Chair in Cancer Research, Deputy Cancer Center Director USC Norris Comprehensive Cancer Center, USC Keck School of Medicine and the national principal investigator on this trial. “The 77% objective response rate observed with onvansertib in combination with standard of care in bev-naïve patients is remarkable, and we look forward to determining the impact that onvansertib can make in the first-line setting.”

“We are proud to be recognized by this prestigious oncology journal for our groundbreaking clinical and preclinical findings observed when adding onvansertib to the standard of care for KRAS mutant mCRC,” added Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. We are highly encouraged by the clinical results demonstrating a 7.7x higher objective response rate (ORR) in patients who were not previously exposed to bev, and our subsequent discovery of a novel mechanism for onvansertib through our translational work. Collectively, these findings and the support of the FDA led us to shift our clinical development program for onvansertib to the first-line setting where all patients are bev-naïve.”

The results of the published Phase 2 clinical trial treating patients with KRAS-mutant mCRC (NCT03829410) demonstrated that onvansertib combined with FOLFIRI and bev was well-tolerated and revealed a greater clinical benefit in bev-naïve patients (ORR of 77%, mPFS of 14.9 months) compared to bev-exposed patients (ORR of 10%, mPFS of 6.6 months). In addition, the company showed the underpinnings of this clinical finding using preclinical models which demonstrated onvansertib inhibited the hypoxia pathway and exhibited robust antitumor activity in combination with bev through the inhibition of angiogenesis. Based on these findings, Cardiff Oncology initiated CRDF-004, a Phase 2 randomized clinical trial of onvansertib in combination with SoC (FOLFIRI and bev or FOLFOX and bev) for the first-line treatment of patients with RAS mutant mCRC. The company anticipates releasing initial data from the CRDF-004 trial in the second half of 2024.

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 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 an epidemic or pandemic such as the 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, 2023, 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:

James Levine
Chief Financial Officer
858-952-7670
jlevine@cardiffoncology.com

Investor Contact:
Kiki Patel, PharmD
Gilmartin Group
332-895-3225
Kiki@gilmartinir.com

Media Contact:
Grace Spencer
Taft Communications
609-583-1151
grace@taftcommunications.com