Cardiff Oncology Announces Positive Initial Data from First-line RAS-mutated mCRC Clinical Trial

December 10, 2024

- Initial results from randomized Phase 2 CRDF-004 trial evaluating onvansertib + standard of care in RAS-mut mCRC demonstrated 64% ORR in the 30mg onvansertib dose arm versus 33% ORR in the control arm -

- In the experimental arms, 30mg dose of onvansertib demonstrated a higher ORR compared to 20mg dose of onvansertib (64% vs. 50%) with deeper tumor regression in the 30mg arm -

- Onvansertib was well tolerated at both doses -

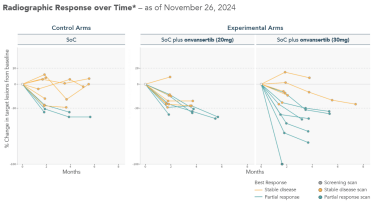
- Additional clinical data from CRDF-004 trial expected in 1H 2025 -

- Company will hold a conference call today at 8:00 a.m. ET / 5:00 a.m. PT -

SAN DIEGO, Dec. 10, 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 positive initial data from CRDF-004, a randomized, Phase 2 clinical trial evaluating onvansertib in combination with standard-of-care (SoC) in patients with first-line RAS-mutated metastatic colorectal cancer (mCRC). Efficacy and safety data are for all evaluable patients as of a November 26, 2024 data cut-off date, and all efficacy data are determined by a blinded, independent central review (BICR) of each patient's tumor scan.

"We are highly encouraged by the robust efficacy signal and favorable safety profile observed with onvansertib plus standard-of-care from the first 30 evaluable patients in our randomized first-line RAS-mutated mCRC CRDF-004 trial," said Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. "Our data shows an objective response rate of 64% in patients receiving the 30 mg dose of onvansertib in combination with standard of care, significantly higher than the 33% objective response rate observed in the control arms of standard of care alone. In addition, as can be seen in the spider plots, we are observing deeper tumor response in patients receiving the 30mg dose of onvansertib compared to those receiving the 20mg dose with similar safety profiles for both doses."

Radiographic Response over Time* - as of November 26, 2024



Note: Radiographic response determined per RECIST 1.1 by blinded independent central review. Spider plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

Study Design

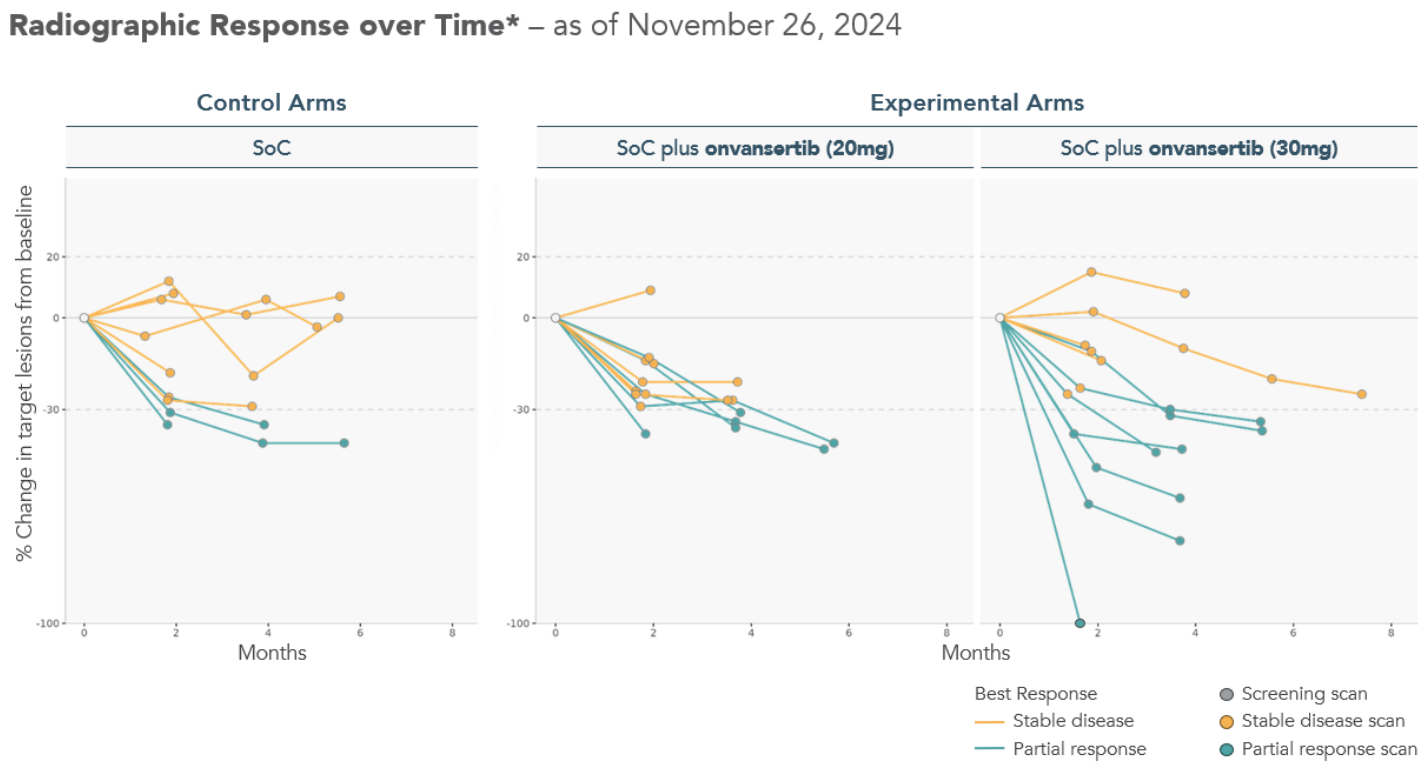
The CRDF-004 phase 2 trial is currently enrolling patients with mCRC who have a documented KRAS or NRAS mutation. Onvansertib is added to SoC consisting of FOLFIRI plus bevacizumab or FOLFOX plus bevacizumab. Patients are being randomized in a 1:1:1 ratio to either 20mg of onvansertib plus SoC, 30mg 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.

Efficacy Data

Objective Response Rates observed in the CRDF-004 clinical trial, as of the data cut-off date of November 26, 2024, are shown below.

Control Arm (SoC alone)	20mg dose of onvansertib + SoC	30mg dose of onvansertib + SoC	All onvansertib patients
33% ORR (3 of 9)	50% ORR (5 of 10)	64% ORR (7 of 11)	57% ORR (12 of 21)

Spider Plots, displaying the change in tumor size from baseline for each patient over time, demonstrate deeper responses observed in patients receiving the 30mg dose of onvansertib in combination with the SoC compared to both the control arms and 20mg dose of onvansertib arms.



Note: Radiographic response determined per RECIST 1.1 by blinded independent central review. Spider plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

Safety and Tolerability

Onvansertib in combination with chemo/bevacizumab was well-tolerated and there have been no major or unexpected toxicities observed.

“Overall, these data support our belief that onvansertib has potential to change the treatment paradigm for the entire first-line RAS-mutated mCRC patient population of almost 50,000 new patients diagnosed in the U.S. annually,” said Mark Erlander, Chief Executive Officer of Cardiff Oncology. “In addition to the efficacy signal observed, the data demonstrate that onvansertib can safely be combined with the two different chemo backbones that are currently approved as standard of care in the first-line setting, thus providing a key differentiated profile over previous generation PLK1 inhibitors. We look forward to providing additional clinical updates from our CRDF-004 trial in the first half of 2025.”

Upcoming expected milestones

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

Conference Call and Webcast

Cardiff Oncology will host a conference call and live webcast at 8:00 a.m. ET / 5:00 a.m. PT on December 10, 2024. Individuals interested in listening to the live conference call may do so by using the webcast link in the "Events" section of the company's website. A webcast replay will be available in the investor relations section on the company's website following the completion of the call.

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, including statements regarding Cardiff Oncology’s plans to provide additional clinical updates from our CRDF-004 trial in the first half of 2025, 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.

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A photo accompanying this announcement is available at

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