Cardiff Oncology Provides Clinical Update on Phase 2 Randomized Second-line ONSEMBLE Trial in Patients with RAS-mutated mCRC

February 29, 2024

- New clinical data from second-line randomized ONSEMBLE trial provides further evidence of the efficacy of onvansertib in combination with FOLFIRI/bev in bev naïve RAS-mutated mCRC patients -

- Company discontinued the ONSEMBLE trial in August 2023 to shift focus of clinical development program to first-line RAS-mutated mCRC in agreement with the FDA -

- Company will hold a conference call today at 4:30 p.m. ET/1:30 p.m. PT -

SAN DIEGO, Feb. 29, 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 provided a clinical update on the first release of data from its second-line RAS-mutated metastatic colorectal cancer (mCRC) ONSEMBLE trial. Although the Phase 2 ONSEMBLE trial was discontinued as part of the company's shift to a first-line mCRC program, it enrolled 23 patients randomized across three arms prior to closing the trial to new enrollment. The 23 enrolled patients continued treatment per protocol. The clinical data repeats the efficacy findings of onvansertib in bev naïve patients seen in the company's earlier Phase 1b/2 KRAS-mutated mCRC trial.

"The randomized data from the ONSEMBLE trial further validates the opportunity for onvansertib in the first-line RAS-mutated mCRC setting. The only objective responses observed on the trial occurred in bev naïve patients who received onvansertib plus standard of care, and the combination of onvansertib with standard of care was well-tolerated. By moving our lead program to the first-line setting, all patients on the CRDF-004 trial will be bev naïve," said Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. "Importantly, no responses were observed in bev naïve patients randomized to the control arm, suggesting onvansertib improved the efficacy of standard of care therapy. And similarly, no responses were observed in patients who had received bev as part of their first line therapy in the onvansertib or the control arms, providing further evidence in a randomized setting of onvansertib's potential to improve outcomes for patients when added to standard of care in the first-line setting. We look forward to sharing the topline results of our first-line CRDF-004 trial in mid-2024."

Data Release from the Phase 2 randomized second-line ONSEMBLE trial in RAS-mutated mCRC

In August 2023, Cardiff Oncology discontinued enrollment in the second-line ONSEMBLE trial to focus on its new lead program in first-line RAS-mutated mCRC. This decision was driven by the fact that both trials essentially test the same clinical hypothesis, the importance of deploying the company's capital efficiently, and the FDA's suggestion that Cardiff Oncology consider focusing on the first-line RAS-mutated mCRC setting given the lack of any new therapies approved in this large cancer indication in the last 20 years.

At the time enrollment was discontinued, the ONSEMBLE trial had randomized 23 patients across three arms including a control arm of standard of care (SoC) FOLFIRI+bev, an experimental arm with onvansertib (20mg dose) added to SoC FOLFIRI+bev, and an experimental arm with onvansertib (30mg dose) added to SoC FOLFIRI+bev. The trial included patients with mCRC who had a documented KRAS or NRAS mutation and had previously received one prior chemotherapy regimen with or without bev in the first-line metastatic setting.

Patient enrollment populations	
Intent to treat population	23 patients
Patient randomized to control arm withdrew consent prior to initial dose	1 patient
Patient population evaluable for safety	22 patients
Patient randomized to control arm withdrew consent prior to post-baseline scan	1 patient
Patient population evaluable for efficacy	21 patients

Efficacy Data – Objective Response Rates (ORR)			
	Bev Naïve patients	Bev Exposed patients	All patients
FOLFIRI/bev (SoC alone); N=6	0% (0 of 3)	0% (0 of 3)	0% (0 of 6)
Onvansertib 20 mg + SoC; N=8	50% (1 of 2)	0% (0 of 6)	13% (1 of 8)
Onvansertib 30 mg + SoC; N=7	50% (1 of 2)	0% (0 of 5)	14% (1 of 7)
Onvansertib (all doses) + SoC; N=15	50% (2 of 4)	0% (0 of 11)	13% (2 of 15)
The two partial responses were confirmed on the patients' subsequent scans.			

Percentage of patients with Grade 4 Treatment-Emergent Adverse Events (TEAEs)	**Grade 4 TEAEs**
Control Arm (SoC alone)	0% (0 of 7)
Onvansertib 20 mg + SoC	25% (2 of 8)
Onvansertib 30 mg + SoC	0% (0 of 7)
Onvansertib (all doses) + SoC	13% (2 of 15)

- The combination of onvansertib with SoC FOLFIRI/bev was shown to be well-tolerated and no major / unexpected toxicities were seen
- Two Grade 4 TEAEs of neutropenia were seen in patients receiving 20 mg Onvansertib + SOC
    - Both patients recovered within 7 and 10 days after withholding the study treatment and no dose reductions in subsequent treatment cycles were needed. Both patients are still on trial

Key Baseline Characteristics

- The patients' median age was 53 years (range 35-81), and 54% were male
- 68% patients had previously received bev in their first-line treatment
- 12 of 21 (57%) evaluable patients remain on trial at the data cutoff date

Conference Call and Webcast

Cardiff Oncology will host a conference call and live webcast at 4:30 p.m. ET/1:30 p.m. PT on February 29, 2024. Individuals interested in listening to the live conference call may do so by using the webcast link in the "Investors" section of the company's website at www.cardiffoncology.com. 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) 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; 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, 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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