Cardiff Oncology Announces First Patient Dosed in ONSEMBLE Phase 2 Randomized Trial of Onvansertib in Patients with Metastatic Colorectal Cancer

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SAN DIEGO, March 28, 2023 /PRNewswire/ -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers, today announced that the first patient was dosed this month with its investigational drug onvansertib in its Phase 2 ONSEMBLE trial (NCT05593328). The trial is designed to demonstrate a clinically meaningful difference in response and onvansertib's contribution to standard of care (SoC) FOLFIRI/bevacizumab for the second line treatment of patients with KRAS/NRAS-mutated metastatic colorectal cancer (mCRC).

"We are excited to be underway with our ONSEMBLE trial that builds on the promising efficacy and tolerability results demonstrated in our phase 1b/2 trial in mCRC," said Fairooz Kabbinavar, MD, Chief Medical Officer of Cardiff Oncology. "mCRC is a difficult-to-treat cancer and patients in the second line setting need novel therapeutic options to improve clinical outcomes. Based on our open-label phase 1b/2 trial, we believe the combination of onvansertib with FOLFIRI/bevacizumab could positively impact patients' responses to treatment and the durability of the responses. Nearly half of our planned 40 sites in the US are open to enroll patients and we've seen great enthusiasm from participating investigators."

The Phase 2 ONSEMBLE trial includes patients with mCRC who have a documented KRAS or NRAS mutation and have previously received one prior chemotherapy regimen with or without bevacizumab in the first line metastatic setting. Patients are being randomized to onvansertib plus FOLFIRI/bevacizumab versus FOLFIRI/bevacizumab (standard of care). The primary endpoint is objective response rate determined by the Response Evaluation Criteria in Solid Tumors via an independent central review. The secondary endpoints include progression-free survival, overall survival, duration of response and safety. The trial is being led by Heinz-Josef Lenz, MD, USC Norris Comprehensive Cancer Center, who has experience with the Company's mCRC clinical program, having served as the principal investigator for the Phase 1b/2 trial.

The Company recently introduced the members of its Scientific Advisory Board, which will continue to provide insight and guidance related to the ONSEMBLE trial and its strategy to advance onvansertib through later-stage clinical development.

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 KRAS/NRAS-mutated metastatic colorectal cancer (mCRC) and metastatic pancreatic ductal adenocarcinoma (mPDAC), as well as in investigator-initiated trials in triple negative breast cancer (TNBC) and small cell lung cancer (SCLC). 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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