Cardiff Oncology Announces First Patient Dosed in Randomized First-line RAS-mutated Metastatic Colorectal Cancer Trial (CRDF-004)

February 29, 2024

- Phase 2 trial in patients with RAS-mutated mCRC will evaluate onvansertib plus SoC versus SoC alone in the first-line setting -

- Pfizer Ignite is responsible for the clinical execution of the trial -

- Initial topline results expected in mid-2024 –

- 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 announced that the first patient was dosed in its randomized first-line Phase 2 trial, CRDF-004, for patients with RAS-mutated metastatic colorectal cancer (mCRC). The trial, whose clinical execution is being conducted by Pfizer Ignite, Pfizer's new end-to-end service for biotech companies, is designed to confirm the dose of onvansertib for a subsequent registrational trial, and generate safety and efficacy data for onvansertib when added to standard-of-care (SoC) vs. SoC alone.

"Today's announcement represents an important milestone for Cardiff Oncology and for patients with RAS-mutated mCRC, who have had no new therapies approved in almost 20 years," said Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. "Based on the encouraging results from our Phase 1b/2 trial in second-line KRAS-mutated mCRC and our preclinical data demonstrating the powerful impact of combining onvansertib and bevacizumab, we believe the addition of onvansertib in the first-line setting has the potential to provide a meaningful improvement to the efficacy of SoC for mCRC patients with a RAS-mutation. We are especially pleased with the opportunity to leverage Pfizer Ignite's execution capabilities to advance the development of onvansertib. We strongly believe that we are on the cusp of a transformative advance in the treatment landscape for mCRC."

The Phase 2 trial includes patients with mCRC who have a documented KRAS or NRAS mutation. Onvansertib will be added to SoC FOLFIRI plus bevacizumab or FOLFOX plus bevacizumab. A total of 90 patients will be 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 and safety.

"We are pleased that the CRDF-004 trial is underway and look forward to providing clinical development support to advance onvansertib in RAS-mutated mCRC, which we believe has the potential to make an impact in patients with metastatic colorectal cancer," said Adam Schayowitz, Ph.D., MBA, Head, Product Teams, Portfolio & Program Management at Pfizer Oncology, and member of Cardiff Oncology's Scientific Advisory Board.

Contingent upon the results of CRDF-004, Cardiff Oncology will initiate a Phase 3, randomized trial, CRDF-005, with registrational intent. The FDA has agreed that ORR at an interim point is an acceptable endpoint to pursue accelerated approval of onvansertib from the CRDF-005 trial, with PFS and trend in overall survival being the endpoints for full approval.

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, 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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