Cardiff Oncology Announces Positive Data from Investigator-Initiated Trial of Onvansertib in Combination with Paclitaxel in Metastatic Triple-Negative Breast Cancer Presented at ASCO 2025

June 2, 2025

– Results from Phase 1b clinical trial evaluating onvansertib + paclitaxel for metastatic triple negative breast cancer demonstrated 40% objective response rate –

– The trial evaluated three doses of onvansertib in combination with paclitaxel, and objective responses were observed only at the highest dose of onvansertib –

– The combination was well-tolerated and demonstrated a safe and manageable toxicity profile –

SAN DIEGO, June 02, 2025 (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 data from an investigator-initiated Phase 1b clinical trial evaluating onvansertib in combination with paclitaxel in patients with metastatic triple-negative breast cancer (mTNBC) at the American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from May 30-June 3, 2025, in Chicago, Illinois.

“Triple-negative breast cancer is among the most aggressive subtypes of breast cancer, and represents a significant unmet medical need for women worldwide. This underscores the urgency to develop novel therapies with enhanced efficacy and improved tolerability for patients with mTNBC,” said Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. “We are highly encouraged by the robust efficacy signal and the tolerable safety profile observed with onvansertib plus paclitaxel in patients with mTNBC. The majority of the patients were heavily pretreated and three of the four objective responses were observed in patients that had prior exposure to paclitaxel. Additionally, we observed a dose-response relationship, with the highest dose of onvansertib resulting in a 40% objective response rate. These findings offer clinical validation of previously reported preclinical data demonstrating synergy between onvansertib and paclitaxel. Overall, we are excited with these results and remain focused on developing onvansertib across multiple cancer types.”

Key highlights from the poster presentation:

Phase 1b Study of PLK1 Inhibitor Onvansertib in Combination with Paclitaxel in Metastatic Triple-Negative Breast Cancer Patients (mTNBC)

- This trial was led by Antonio Giordano, MD, PhD at Dana-Farber Cancer Institute, a principal teaching affiliate of Harvard Medical School.
- The objective of this dose escalation study was to evaluate the safety, pharmacokinetics, and pharmacodynamics of the combination of onvansertib and paclitaxel, a potential new drug combination for the treatment of mTNBC.
- The study’s primary endpoint was safety and characterization of dose limiting toxicities (DLTs) of onvansertib plus paclitaxel and determination of recommended Phase 2 dose (RP2D). The secondary endpoints included pharmacokinetics and pharmacodynamics of onvansertib plus paclitaxel.
- Patients enrolled in the trial received a median of 3 prior lines of chemotherapy.
- Onvansertib in combination with paclitaxel demonstrated 40% objective response rate by RECIST 1.1 at RP2D of 18mg/m^2 (n=10), with two confirmed partial responses and two unconfirmed partial responses.
- The combination of onvansertib and paclitaxel was well-tolerated demonstrated a safe and manageable toxicity profile with myelosuppression being the most common adverse event.
- Collectively, this clinical data further supports the potential exploration of the combination of onvansertib plus paclitaxel for the treatment of mTNBC.

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 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, 2024, 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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