Cardiff Oncology Announces New Patent with Claims for the Use of Onvansertib in Treating KRAS mutated mCRC

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- Protects the use of onvansertib in combination with standard of care in the KRAS mutated mCRC setting through 2043 -

SAN DIEGO, Nov. 19, 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 the United States Patent and Trademark Office (USPTO) has issued to Cardiff Oncology U.S. patent No. 12,144,813 with an expected expiration date of no earlier than 2043. The claims of the patent cover the method of using onvansertib in combination with bevacizumab (bev) for the treatment of KRAS mutated metastatic colorectal cancer (mCRC) patients who have not previously been treated with bev.

"We are pleased to announce the strengthening of our intellectual property portfolio for onvansertib, an important milestone in our mission to advance this innovative therapy to the first-line setting in combination with standard of care for RAS-mutated mCRC patients," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "This newly issued patent underscores the groundbreaking nature of our discovery—demonstrating that onvansertib has the potential to significantly enhance treatment efficacy for KRAS mutated mCRC patients who have not been previously treated with bev."

Onvansertib, a PLK1 inhibitor, is currently being evaluated in a first-line Phase 2, randomized, open-label trial (CRDF-004) in combination with FOLFIRI and bev or FOLFOX and bev for the treatment of mCRC patients with a RAS mutation, and an initial data readout is expected by the end of 2024.

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 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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