Cardiff Oncology Announces a Second Patent for the Treatment of mCRC for Bev-Naïve Patients

April 23, 2025

The claims cover combination treatment of onvansertib + bev for all bev-naïve patients including RAS-mutated and RAS wild type mCRC across all lines of therapy through 2043

SAN DIEGO, April 23, 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 that the United States Patent and Trademark Office (USPTO) has issued to Cardiff Oncology U.S. patent No. 12,263,173 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) in any line of therapy for the treatment of metastatic colorectal cancer (mCRC) patients who have not previously been treated with bev.

“The expansion of our intellectual property portfolio strategically positions onvansertib for broader market opportunities and future growth,” said Mark Erlander, Chief Executive Officer of Cardiff Oncology. “While our current lead program in mCRC focuses on the first-line RAS-mutated patient population, the claims in this patent cover the broader applicability of onvansertib for bev naïve mCRC patients across all lines of therapy. Additionally, last fall the USPTO issued to us a patent with claims covering the use of onvansertib for the first-line treatment of bev naïve patients with a KRAS mutation. Building upon this, the newly issued patent encompasses all mCRC patients, with RAS-mutated or RAS wild-type mCRC. Overall, we believe the extensive applicability of onvansertib has the potential to drive widespread adoption, facilitate seamless integration into clinical practice, and potentially redefine the standard of care for the treatment of mCRC.”

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. Cardiff Oncology announced initial data from the ongoing CRDF-004 trial in December, 2024. Additional clinical data from the trial is expected in 1H of 2025.

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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